2013-1624, 2014-1012

IN THE

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

TYCO HEALTHCARE GROUP LP AND
UNITED STATES SURGICAL CORPORATION,

Plaintiffs-Cross Appellants,

v.

APPLIED MEDICAL RESOURCES CORP.,

Defendant-Appellant.

Appeals from the United States District Court for the Eastern District of Texas in Case No. 09-cv-0176 Magistrate Judge Keith F. Giblin

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BRIEF OF PLAINTIFFS-CROSS APPELLANTS TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORPORATION

JACOB A. SCHROEDER
FINNEGAN, HENDERSON, FARABOW
GARRETT & DUNNER, LLP
3300 HILLVIEW AVENUE
Palo Alto, CA 94304-1203
(650) 849-6600

J. MICHAEL JAKES
KATHLEEN A. DALEY
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiffs-Cross Appellants Tyco Healthcare Group LP and United States Surgical Corporation

January 30, 2014

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Cross Appellants Tyco Healthcare Group LP and United States Surgical Corporation certify the following:

1. The full name of every party or amicus represented by us is:

Tyco Healthcare Group LP (doing business as Covidien)
United States Surgical Corporation

2. The name of the real party in interest represented by us is:

Tyco Healthcare Group LP (doing business as Covidien)
United States Surgical Corporation

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are:

Covidien plc

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by us in the trial court or agency or are expected to appear in this Court are:

Peter J. Armenio
Mark D. Baker
Sandra A. Bresnick
Richard W. Erwine
Laura L. Fairneny
Faith E. Gay
Benjamin J. Gildin
Benoit Quarmby
Krista M. Rycroft
QUINN EMANUAL URQUHART & SULLIVAN, LLP

John M. Desmaris
Paul A. Bondor
DESMARIS LLP

Andrew T. Gorham
Ellen A. Scordino
FISH & RICHARDSON PC

Claude Edward Welch
LAW OFFICE OF CLAUDE E WELCH

Jon R. Carter
Ryan H. Coletti
Jason S. Grauch
Michael J. Gulliford
Kathryn M. Liberatore
Marjorie P. Lindblom
Young J. Park
Michael D. Reisman
Howard D. Shatz
Ephraim Starr
Sarah K. Tsou
KIRKLAND & ELLIS, LLP

Robert M. Parker
Robert Christopher Bunt
Charles Ainsworth
PARKER BUNT & AINSWORTH, P.C.

Kathleen A. Daley
J. Michael Jakes
Jacob A. Schroeder
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP

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STATEMENT OF RELATED CASES

No appeal in or from the same civil action was previously before this or any other appellate court. Counsel are not aware of any case that may be directly affected by this Court's decision.

STATEMENT OF JURISDICTION

(a) The statutory basis for jurisdiction of the trial court was 28 U.S.C. § 1338(a).

(b) The statutory basis for jurisdiction of this Court to hear the issues raised in this cross-appeal is 28 U.S.C. § 1295(a)(1), the district court having issued a final judgment on September 4, 2013.

(c) This cross-appeal was timely filed on October 3, 2013, in accordance with 28 U.S.C. § 2107 and Fed. R. App. P. 4(a).

I. STATEMENT OF THE ISSUES

A. Applied's Appeal

1. Whether the district court's construction of the term "minimize" in the Smith '377 patent as meaning "reduce" is correct when it is supported by the claim language, the specification, and extrinsic evidence?

2. Whether the jury's verdict finding that Applied's trocars infringe the Smith '377 patent is supported by substantial evidence when Applied agreed that its trocars meet all structural limitations of the claims and only challenged a functional limitation, and when testimony of Applied's witness, Applied's documents, and testimony from Tyco's expert amount to substantial evidence of infringement?

B. Tyco's Cross-Appeal

1. Whether the district court's construction of the "means engageable" limitation of the Green '143 patent is erroneous because it is not limited to the corresponding structure described in the specification and linked to the claimed function?

2. Whether the district court's refusal to construe the dual-rigidity limitation of the Smith '377 and '702 patents improperly left claim construction up to the jury?

II. STATEMENT OF THE CASE

A. Preliminary Statement

Plaintiffs-Cross Appellants Tyco Healthcare Group LP and United States Surgical Corporation (collectively, "Tyco") have long been the leader in the field of surgical instruments. In particular, Tyco has been an innovator in the field of instruments used for minimally invasive or laparoscopic surgery, including surgical trocars. During such a procedure, a trocar is introduced into a patient's abdomen, and a surgeon can then introduce other instruments through the trocar. It is important that the trocar have a valve that both permits instruments to pass through and provides a fluid tight seal.

Tyco developed new and unique valve assemblies for surgical trocars that allowed instruments to be passed through with less force while providing improved sealing. These inventions led to two families of patents: Smith and Green. The Smith patents are U.S. Patent Nos. 5,603,702 ('702 patent) and 5,895,377 ('377 patent). The Green patents are U.S. Patent Nos. 5,304,143 ('143 patent) and 5,685,854 ('854 patent). Because Applied has been using Tyco's technology, Tyco sued Applied, accusing Applied's Universal Seal and Kii trocars of infringing certain claims of the Smith and Green patents.

The procedural history of this matter is complex: a record spanning more than seven years; two separate two-week jury trials each involving separate sets of

products accused of infringing different subsets of claims from the Smith and Green families; multiple rounds of claim construction; and now appeals by both parties. The core patent law issues, however, are simple and straightforward: claim construction and whether substantial evidence supports the jury verdict.

Applied appeals (1) the district court's construction of "minimize" in the Smith '377 patent, and (2) whether substantial evidence supports the jury's verdict of infringement of that patent. The court's construction of "minimize" to mean "reduce," however, should be affirmed because the Smith patents describe the reduction in insertion force as being general in nature, not a reduction to the minimum possible under the circumstances. Applied also argues that the jury's verdict of infringement should be overturned, but Tyco presented substantial evidence of infringement, including the testimony of its expert supported by Applied's documents and testimony from Applied's witnesses. Moreover, Tyco demonstrated to the jury that Applied's testing was flawed.

On cross-appeal, Tyco challenges (1) the district court's construction of a means-plus-function limitation in the Green '143 patent as being too broad, and (2) the court's failure to construe disputed terms in the Smith patents and Applied's improper claim-construction arguments to the jury. First, the district court misread the Green '143 specification when it found that a corresponding structural requirement was not linked to the claimed function. The court's broad claim

construction permitted the jury to ignore important structural distinctions between claims 12 and 13 of the Green ’143 patent and the prior art—distinctions expressly noted in the ’143 specification and recognized by the Patent Office in an interference involving a Green patent. Second, before and during trial, Tyco sought construction of limitations in the Smith patents reciting that the valve include elongated guard members having portions with differing rigidity. But the district court refused, saying that the limitations would be given their plain and ordinary meaning. Nonetheless, Applied repeatedly argued to the jury that the claim scope was limited to differing thicknesses rather than differing rigidities. As a result, the court erred by letting the jury decide the meaning and scope of the dual-rigidities limitation.

B. Course of Proceedings

Tyco filed its original complaint in July 2006 (CA No. 06-cv-151) and refiled, after adding United States Surgical as co-plaintiff, in October 2009 (CA No. 09-cv-176). The issues were bifurcated between two separate jury trials, the first in March 2010 and the second in September 2011.

The March 2010 trial concerned Applied’s products sold before 2006. The issues were infringement of claim 6 of the Smith ’377 patent and validity of claims 12 and 13 of the Green ’143 patent. The jury found (1) Applied’s accused trocars infringe claim 6 of the Smith ’377 patent and awarded Tyco $4,810,389 in

damages, and (2) claims 12 and 13 of the Green ’143 patent are invalid for obviousness.

Following the March 2010 trial, Tyco asserted claims 14 and 31 of the Green ’143 patent and claims 4 and 5 of the Green ’854 patent against Applied’s next-generation products, sold after Tyco’s original complaint. Applied moved for summary judgment, arguing that the Green patents are invalid based on collateral estoppel, even though the newly asserted claims were not litigated in the March 2010 trial. The district court granted Applied’s motion and held the newly asserted claims from the Green patents invalid.

A second trial was held in September 2011. Because the district court granted summary judgment of invalidity on the Green patents, the only remaining issues were the infringement and validity of claims 1 and 2 of the Smith ’377 patent and claims 1 and 5 of the Smith ’702 patent. The jury found each claim not infringed and invalid.

The district court entered final judgment on September 4, 2013. Both parties appealed.

III. COUNTERSTATEMENT OF FACTS FOR APPLIED’S APPEAL

A. The Smith ’377 Patent

The Smith ’377 patent set out to solve a fundamental problem in the prior art: because prior-art trocars used thick valve members, i.e., elastic seals, to

maintain a fluid-tight seal, "the level of force needed to insert and advance the instrument through the seal aperture is increased." JA146 at 2:54-62. The '377 patent provides a trocar that can both maintain a fluid-tight seal and "enhance and facilitate passage of the instrument through the valve unit." JA147 at 3:1-7. Specifically, the '377 patent claims a trocar valve assembly having a plurality of guard members where each guard member has an end portion that is more flexible than the rest of the guard member.

With the disputed element emphasized, claim 6 of the '377 patent recites:

> 6. A valve assembly for sealed reception of an elongated object, which comprises:
>
> (a) a valve housing having a longitudinal opening configured and dimensioned to permit entry of an elongate object;
>
> (b) an elongated resilient seal member at least partially positionable within the valve housing and defining an aperture to permit entry of the elongated object therein in [a] substantially fluid tight manner; and
>
> (c) a plurality of guard members disposed within the seal member and concentrically arranged about a central longitudinal axis defined by the valve housing and positioned to engage the elongated object upon insertion of the elongated object within the valve housing, the guard members arranged such that at least end portions of adjacent guard members are in overlapping relation, each guard member adapted to be radially displaced during introduction of the elongated object within the valve assembly to contact portions of the valve member adjacent, but proximal to, the aperture to facilitate passage of an elongated object therethrough, the end

> portions of the guard members being substantially flexible relative to the remaining portions of the guard members *to effectively minimize force required to advance the elongated object through the guard members*.

The Smith ’377 patent overcomes the disadvantages of the prior art by using strategically dimensioned guard members: “Each guard member possesses an end portion of less rigidity than the remaining portion(s) of the guard member wherein the end portion of less rigidity reduces the forces required to advance the elongated object through the valve housing.” JA147 at 3:58-62. Figure 8A shows an embodiment of these guard members:

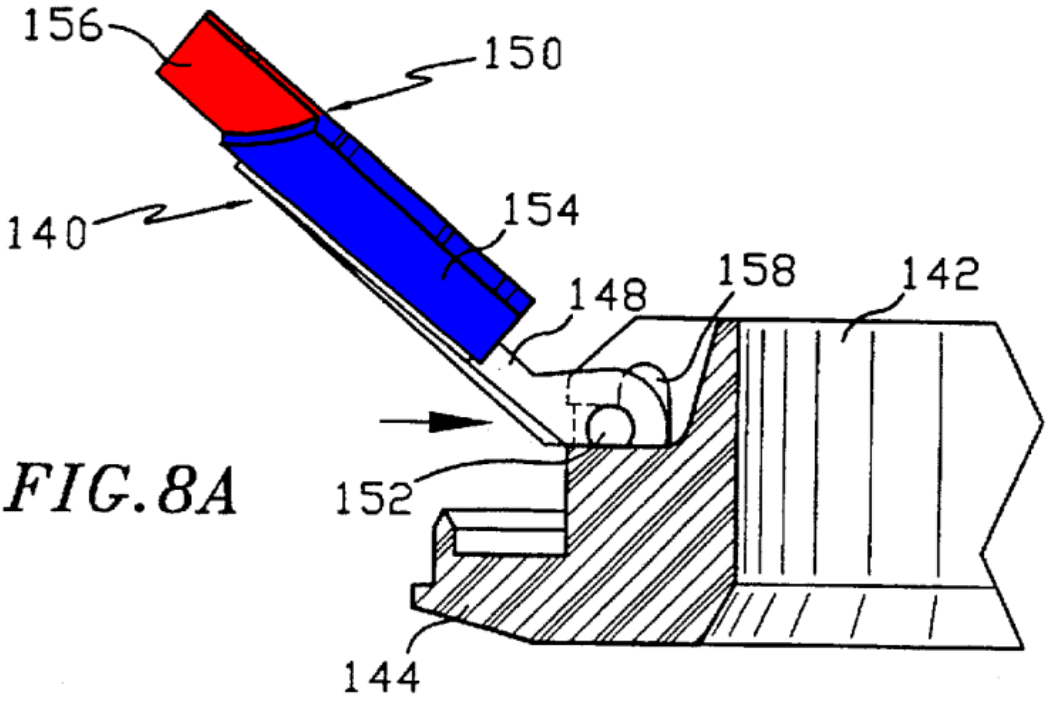


FIG. 8A

Figure 8A illustrates the following components:

- **Guard member**: the guard member 140 includes a flap portion 150.

- **More rigid portion**: one portion of the guard member (portion 154 highlighted in blue) is more rigid than another portion. In a preferred embodiment, this portion is about two to three times thicker than the thinner portion. JA149 at 7:20-22.

- **Less rigid portion**: one portion of the guard member (portion 156 highlighted in red) is less rigid than the other portion.

The guard member is dimensioned so that the more rigid portion stretches the valve open while the "less rigid, second portion 156 of outer flap 150 reduces the force required to pass the instrument through the guard mount and seal arrangement." *Id.* at 7:34-45. "[T]he particular dimensioning of the guard elements 140, i.e., the rigid section in combination with the more flexible outer portion, ensures adequate stretching of the seal element 110 while also permitting relatively easy passage of instrument 400 through the valve assembly." JA150 at 10:44-49. In other words, the dual-rigidity guard members reduce insertion force.

B. The Court's Construction of "Minimize"

The parties disputed the meaning of the word "minimize" in claim 6 of the Smith '377 patent. Tyco and Applied agreed that "minimize" means "reduce," but disputed the amount of reduction that the claim requires. Tyco proposed that "effectively minimize" means sufficiently reducing the force. JA1543. Focusing on the word "minimize," Applied argued that the claim should be construed to mean that the force is reduced "to the minimum level possible under the circumstances." *Id.*; Applied Br. at 29-30.

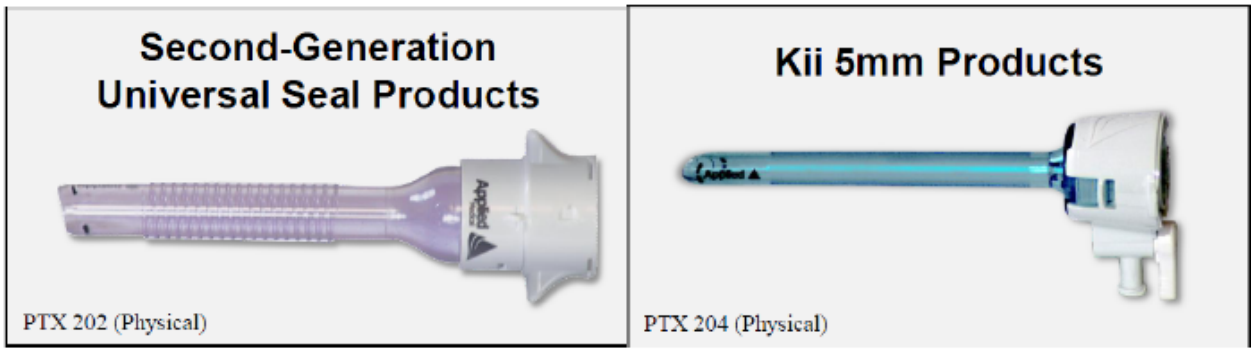
The district court construed "effectively minimize" to mean "effectively reduce," so that the entire clause was construed to mean "the end portions of the guard members being substantially more flexible than the remaining portions of the guard members so as to effectively reduce the force required to insert the elongated object." JA34. In declining to add that the force must be reduced "to the minimum level possible," the court relied on the claim language and the specification. JA32-34. The court noted that the '377 patent specification states that the guard members "provide sufficient flexibility to minimize the force required to advance the instrument through the guard element and seal arrangement," and "also states 'the relatively thin and less rigid second portion 156 of outer flap 150 reduces the force required to pass the instrument through the guard mount and seal arrangement.'" JA33. The district court concluded that "all that is claimed is that the force is reduced by including flexibility at the end portions of the guard members," not "that force cannot be reduced further." JA34.

After expert reports were submitted, Applied sought clarification of the construction in response to an issue it perceived from Tyco's expert report on validity. JA5506-07; JA5810. The court clarified its construction that "[t]he end portions of the guard members are substantially flexible, relative to the rest of the guard members, in such a way that effectively reduces the force required to

advance an elongated object through the guard members." JA103; JA59. Applied later stipulated to the validity of claim 6 of the '377 patent. JA8744-45.

C. March 2010 Trial

The parties tried infringement of claim 6 of the '377 patent by Applied's trocars (shown below) to the jury in March 2010.



Applied's expert agreed that the accused trocars meet the structural limitations of claim 6. JA11186:15-JA11193:11. In other words, Applied did not dispute that its guard members satisfied the structural limitation that "[t]he end portions of the guard members being substantially flexible, relative to the remaining portions of the guard members." JA11191:24-JA11192:21. Instead, Applied only disputed whether the functional effect of this structural limitation was met. JA11194:2-11. Specifically, Applied disputed whether, under the district court's construction, the end portions of the guard members were flexible "in such a way that effectively reduces the force required to advance an elongated object through the guard members." *Id.*; JA103. The jury found that Applied's accused trocars met this limitation. JA73.

1. Tyco's Expert Testified that the Accused Products Meet the Functional Limitation

At trial, Tyco's infringement expert, William Dubrul, testified that Applied's trocars meet the functional limitation that the end portions of the guard members are flexible "in such a way that effectively reduces the force required to advance an elongated object through the guard members." *See, e.g.*, JA10010:14-JA10012:22. Mr. Dubrul based his opinion on an analysis of Applied's products and documents. *See, e.g.*, JA9966:18-JA9967:9. He discussed the evolution of Applied's product line from fingerless trocars to trocars using dual-rigidity fingers. JA9978:1-JA9999:10. He explained that Applied's First Generation Universal Seal trocars lacked fingers and, according to Applied's internal testing, "[did] not sufficiently reduce the drag force encountered when placing or removing instruments through the septum seal." JA9978:6-JA9980:12.

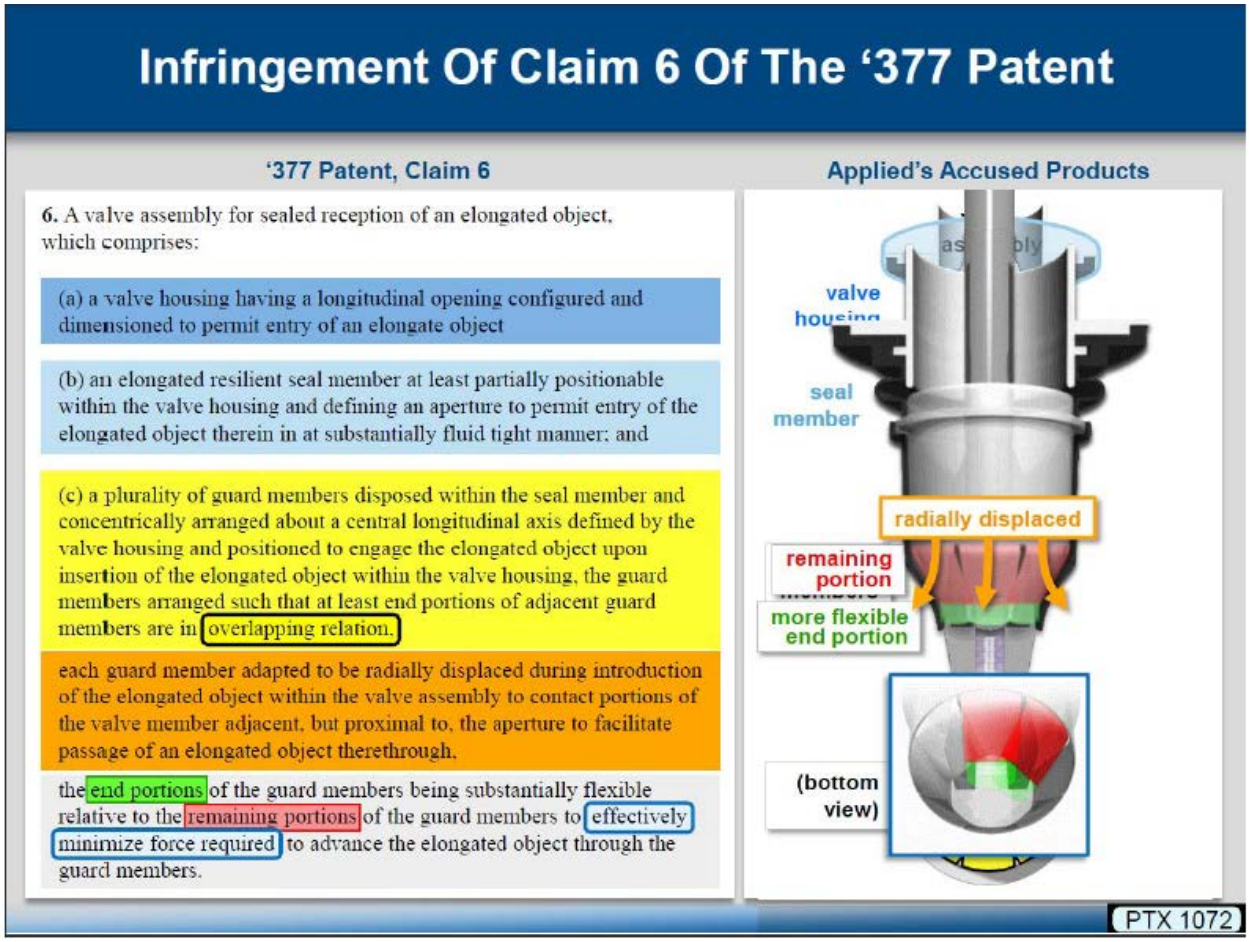
To solve that problem, Applied modified its First Generation Universal Seal trocars by adding eight polyethylene dual-rigidity fingers to create the Second Generation Universal Seal trocars—those accused of infringement. JA9984:25-JA9986:4. Applied's internal studies showed that the fingers in these trocars reduce the drag force of inserting an instrument through the guard member over fingerless devices. JA9986:11-JA9987:2; JA9994:4-22. Applied's internal emails also described its trocars as "dramatically" reducing the friction necessary to insert an instrument through them. JA9990:20-JA9992:20. Mr. Dubrul discussed

Applied's sales-training manuals, which described the accused trocars as reducing instrument drag. JA9992:21-JA9995:13.

Applied even tried to patent its trocar design in 2004. In its patent application, Applied described trocars with guard members having two distinct portions with differing flexibility. JA28560 ("In another aspect, the distal tip of each of the blades may further comprise a first material having a first durometer and a second material distal to the first material having a second durometer."). Applied alleged that a benefit of this design is that it "reduce[d] the drag force encountered when placing or removing instruments through the seal." JA28559. Applied also recognized that, by modifying the flexibilities of two portions of the fingers, a trocar designer could "control the behavior of the shield as instruments and tools come into contact with it." JA28568. Applied let its application go abandoned, however, after the claims were rejected as anticipated and obvious in view of the Smith '377 patent. JA28690-94; JA28699.

Mr. Dubrul also testified about his experimental testing. JA10016:11-JA10023:25. He explained his "cantilever beam test," which set out to quantify the difference in flexibility between the thinner portion of the fingers and the thicker portions. According to Mr. Dubrul's tests, the thinner portion "required 60 percent less force to bend" compared to the thicker portion. JA10021:1-25. Mr. Dubrul further testified that, all things being equal, his tests conclusively establish that it

would take less force to push through the thinner tips of the fingers than it would to push through uniform, thicker fingers. JA10023:19-JA10023:25. He also explained that this would be true even if the seal was added to the fingers. JA10148:5-JA10149:4. Mr. Dubrul passed around samples of the accused products for the jury to view as he explained his infringement opinion element-by-element. *See, e.g.*, JA9987:5-JA9989:12.



Based on this evidence and his nearly twenty years of experience in designing trocars, Mr. Dubrul testified that Applied's trocars met the requirement

that the guard members "effectively minimize the force required to advance the elongated object through the guard members." *See, e.g.*, JA10010:14-JA10013:16.

2. The District Court Modified Its Construction Midtrial

After Mr. Dubrul's testified, Applied sought further clarification of the following limitation and construction (disputed words emphasized):

Claim language	adapted to be radially displaced during introduction of the elongated object within the valve assembly to contact portions of the valve member adjacent, but proximal to, the aperture to facilitate passage of an elongated object therethrough
Court's construction	A portion of each guard member *may* be moved in a direction away from the longitudinal axis during introduction of the elongated object to contact the valve adjacent, but proximal to the aperture, to assist passage of the elongated object *therethrough*.

Specifically, Applied sought clarification on the words "may" and "therethrough." JA9035. The court clarified its construction by further construing "may" to mean "has the ability to" and "therethrough" to mean "through the aperture." JA11134:17-JA11139:18. The court's clarified construction (showing changes from the prior construction) provides:

Clarified construction	A portion of each guard member may <u>(has the ability to)</u> be moved in a direction away from the longitudinal axis during introduction of the elongated object to contact the valve adjacent, but proximal to the aperture, to assist passage of the elongated object ~~therethrough~~ <u>through the aperture</u>.

JA103; JA11134:17-JA11139:18.

3. Applied's Expert Agreed that the Accused Trocars Meet the Modified Construction

After the district court further clarified its construction, Applied's expert, Dr. Gerald Miller, took the stand. He admitted that this claim limitation (pursuant to the clarified construction) was literally met by Applied's accused trocars. He was asked whether "each guard member [is] adapted to be radially displaced during introduction of the elongated object within the valve assembly to contact portions of the valve member adjacent, but proximal to, the aperture to facilitate passage of an elongated object therethrough." JA11190:14-20. Dr. Miller stated that this feature was "fairly common for a number of trocars, including . . . in the Applied products." JA11191:1-22.

Dr. Miller confirmed that his disagreement with Mr. Dubrul instead came down to whether Applied's guard members "effectively minimize force required to advance the elongated object through the guard members." JA11193:5-JA11194:11. While Applied's documents confirm that the guard members reduce the force required to advance an elongated object through the guard members (*see, e.g.*, JA9986:11-JA9987:2; JA9994:4-22), Dr. Miller testified that any reduction in force was not caused by the thinned portions of the guard members. JA11170:14-JA11172:17; JA11185:16-JA11186:6. Dr. Miller criticized Mr. Dubrul's tests as failing to take into account the presence of the elastomeric seal, since those tests

were conducted without the elastomeric seal.[1] JA11175:20-JA11176:2. At the same time, Dr. Miller agreed that the thinner end portions will be more flexible and require less force to bend than thicker ones. JA11197:6-11. He said that, with air in the background, something thinner is easier and would require less force to get through than something thicker. JA11210:4-18.

4. Applied's Expert Testing Was Flawed

Applied also had Dr. Harry Hogan testify on whether the end portions of the guard members in Applied's trocars reduce insertion force. Dr. Hogan purported to compare insertion forces for trocars having guard members with uniform thickness to the accused trocars with guard members having thinned tips. Although Dr. Hogan testified that his test results showed that the thinner tips in Applied's accused trocars do not reduce insertion force, his testing was flawed.

This was Dr. Hogan's first experience with trocars. JA11310:11-18. He relied on samples specially created by Applied under a protocol dictated by Applied and inconsistent with normal usage. JA11315:4-14; JA11321:10-19; JA11329:20-25. To carry out his tests, Dr. Hogan inserted an instrument in the trocars at a rate of 10 inches per minute, rather than at the rate a doctor actually

[1] Mr. Dubrul also conducted tests confirming that, even with the elastomeric seal in place, the force was still reduced, but the district court precluded him from presenting those tests to the jury. JA7255; JA7258-59; JA7283-84; JA8609-16.

uses. JA11328:24-JA11329:19; JA11331:12-18. In fact, Dr. Hogan performed his tests at a rate that was three times slower than a snail (which moves at 31 inches per minute) and four times slower than the rate a doctor would use (which is 40 inches per minute). JA11323:8-16; JA11328:24-JA11329:3. The speed that Dr. Hogan used was also slower than the rate Applied uses in its own internal tests on regular products. JA11331:15-18. Despite acknowledging that the rate a surgeon uses was a relevant consideration, Dr. Hogan admitted that he did not conduct any tests at a rate of 40 inches per minute or any other rate similar to how a surgeon actually uses these devices. JA11328:24-JA11329:3.

In performing his tests, Dr. Hogan also inserted the instrument into the trocar in a straight vertical alignment, rather than off-axis as a surgeon would actually do. JA11330:1-JA11331:5; JA11331:19-24. Notably, Applied's expert, Dr. Robert Sewell; Applied's engineer, Charles Hart; and Dr. Pat Reardon (another laparoscopic surgeon) all said that it would never happen (or that it would be "very, very, very seldom") that an instrument is inserted vertically right down the middle. JA11330:11-17.

5. On Rebuttal, Mr. Dubrul Again Testified that the Functional Limitation Was Met

Since the district court had modified the claim construction after Mr. Dubrul testified, it allowed him to testify again. JA11232:14-19; JA11539:4-13. Mr. Dubrul testified that the court's clarified construction did not change his opinion.

JA11540:22-JA11541:13. Specifically, as it concerned the "may" and "therethrough" modifications, Mr. Dubrul pointed out that Dr. Miller agreed with his analysis that this limitation was met. JA11546:15-JA11547:13. Mr. Dubrul noted that the disagreement came down to the functional requirement—whether the reduction in insertion force was caused by the thinned ends of the guard members in the accused products. JA11547:8-13.

Mr. Dubrul testified that the flexible tips of the guard members resulted in a significant reduction of force for an instrument passing through the guard members and through the guard members and the aperture. *See* JA11553:23-JA11554:1. While holding one of Applied's trocars in his hands and demonstrating to the jury, he explained its operation and how the thinner tips of the fingers "slide apart and they facilitate entry with reduced force down through the septum." JA11551:13-JA11552:1.

Mr. Dubrul explained how, all things being constant, it would be easier to advance an instrument through the thinner guard members than through guard members having a uniform thickness. JA11551:13-JA11553:7. He discussed the tests he performed on the guard members and explained that adding the septum seal was a constant that would not change his analysis. JA11553:8-JA11556:20. Mr. Dubrul concluded that it "require[d] less force to get through thinner material and the constant seal versus thicker material and the constant seal." JA11576:3-17.

He further confirmed that, even if the seal had a variable hoop strength, it would still be a constant that would not impact his analysis. JA11579:2-11.

Mr. Dubrul's testimony that it would be easier to advance an instrument through the thinner guard members than through guard members having a uniform thickness was supported by Dr. Miller's testimony, as well as the testimony of Jeremy Albrecht, an Applied engineer. Specifically, Mr. Albrecht testified:

> Q. And you would agree with me that if we took a constant force of any kind, it's going to take more force to push through something that's thicker than if I try to push through something that's thinner, correct? Simple physics, mechanics, that's always true, right?
>
> A. Holding everything else constant, yes.
>
> Q. That's always true, right?
>
> A. Holding everything else constant, that would be a true statement.
>
> Q. Holding everything else constant, it's not a subject for debate; it's simple, straightforward physics, mechanical engineering. It's easier to use a force to get through something that's thinner than something that's thicker, right?
>
> A. Yes.
>
> Q. You would never dispute that as an engineer. You would accept it completely, holding everything else constant, correct?
>
> A. Yes.

JA10872:25-JA10873:18.

6. The Jury Found Infringement

The jury returned a verdict finding that Applied's trocars infringe claim 6 of Tyco's Smith '377 patent, and that Tyco was entitled to a reasonable royalty of $1 per unit, totaling $4,810,389. JA73; JA75.

IV. STATEMENT OF FACTS FOR TYCO'S CROSS-APPEAL

A. The Green '143 Patent

The Green '143 patent concerns a trocar with two valve members and flexible fingers. The fingers were claimed using means-plus-function language, which is central to the parties' dispute. With the relevant limitation emphasized, claim 12 recites:

> 12. Valve assembly for introduction of an elongated object into a patient's body, which comprises:
>
> a) valve body member defining a proximal inlet opening and a distal outlet opening;
>
> b) first valve member formed of a flexible elastomeric resilient material and defining an aperture for reception of the elongated object, said aperture being configured and dimensioned such that insertion of the elongated object into said aperture causes said flexible resilient material defining said aperture to resiliently engage and conform to an outer surface portion of the elongated object in substantially fluid tight manner;
>
> c) second valve member positioned adjacent said first valve member and in general alignment therewith, said second valve member defining an aperture in general alignment with said aperture of said first valve member, and being formed of a flexible resilient material at least in the region adjacent to and defining said aperture; and

d) *means engageable with the elongated object upon insertion thereof into said proximal inlet opening of said valve body member, and adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein.*

The Green '143 specification discloses a single embodiment for the "means engageable" limitation. Figure 4 of the preferred embodiment, is shown highlighted below and depicts the "means engageable" structure. JA180.

FIG. 4

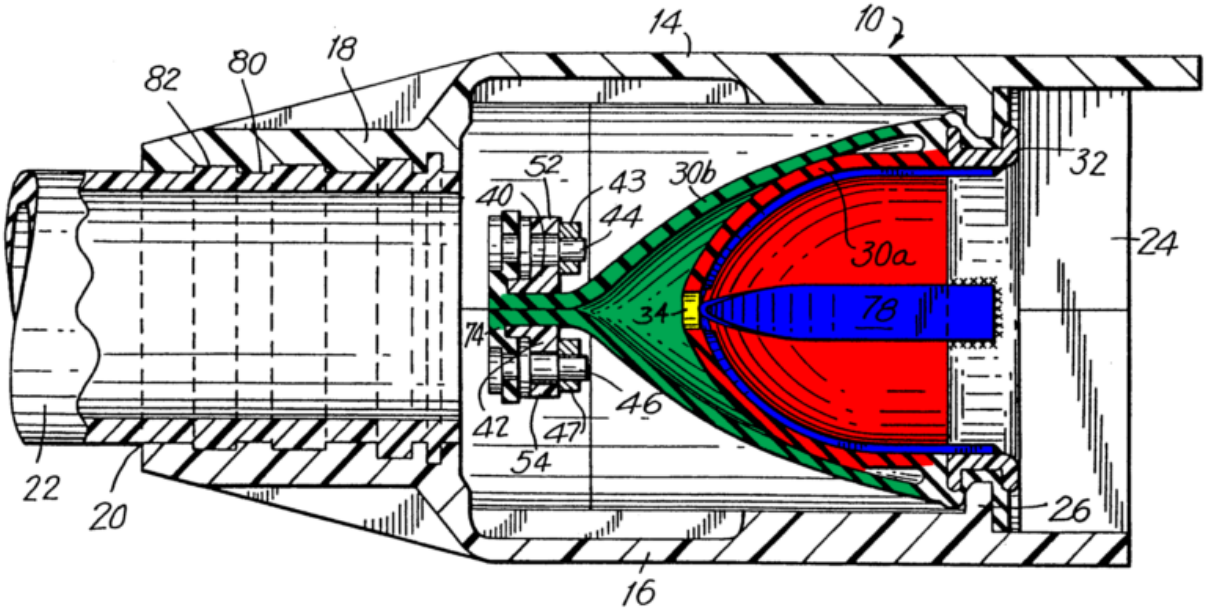


Figure 4 illustrates the flexible fingers 78 (highlighted in blue) which engage with an inserted instrument and spread the valve member 30a (highlighted in red) to expand the aperture 34 (highlighted in yellow). Another valve member 30b is shown highlighted in green. When assembled, the fingers "are sufficiently thin and flexible such that insertion into inner wall 30a of diaphragm 30 causes them to

assume an initial arcuate shape" as shown above in Figure 4. JA183 at 6:55-61. The fingers "are sufficiently flexible to conform to the shape of the inner wall." *Id.* at 6:42-45. This structural characteristic is by design. The function of the fingers is to "assist in spreading inner wall 30a to expand aperture 34 when an instrument is inserted," and the fingers perform this function "by distributing the spreading force [along inner wall 30a] more evenly" due to their conformity to the inner wall. *Id.* at 6:46-48. These flexible fingers were distinguished from prior art containing rigid "finger operated levers." JA181 at 2:24-2:34.

1. Flexible "Fingers" Are Patentably Distinct from Rigid Finger-Like Levers

Tyco filed a continuation application from the Green '143 patent, which issued as the Green '854 patent. JA189. During prosecution of the '854 patent, Tyco sought to provoke an interference with an Applied patent that had issued. JA28929. The count of the proposed interference included a means-plus-function element relating to the "fingers" disclosed in the '143 patent. *Id*. The element was "means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area." *Id*. Both Tyco and Applied argued to the Patent Office that, "despite identical wording of [Tyco]'s claims 34-42 and [Applied]'s claims . . . there is no interference-in-fact because of different construction of 'means-plus-function' claim limitations under 35 U.S.C. § 112, sixth paragraph." JA28930. In other words, because Tyco's specification and

Applied's specification described different structures for performing the recited function, there was no interference-in-fact. Applied's specification described "[a] plurality of levers" that pivot about an axis. *See, e.g.*, JA26125 at 4:35-JA26126 at 5:21.

The Patent Office agreed that flexible fingers differed from rigid levers. According to the Patent Office, "[Tyco]'s soft, thin, and flexible 'fingers' conforming to the conical shape of the valve's inner membrane primarily provides a passive protective coating for the membrane and not a mechanism for actively enlarging the orifice." JA28932. The Patent Office further elaborated on the differences between the flexible fingers of the '143 patent and the rigid, finger-like levers:

> While [Tyco]'s thin and flexible "fingers" may assist in enlarging the orifice by distributing the expansive force and spreading it throughout the membrane material when an instrument contacts the fingers, [Applied]'s rigid levers concentrate and focus the enlarging force in the lateral direction and with a mechanical advantage not obtainable with [Tyco]'s soft and flexible "fingers." While the orifice enlargement or orifice friction reduction effected through [Tyco]'s fingers is generally passive, indirect, delayed, and almost incidental, the same effected through [Applied]'s rigid levers is active, direct, immediate, and most deliberate. *Given either structure or configuration as prior art, the other would not have been obvious to one with ordinary skill in the art.*

JA28935 (underlined emphasis in original; other emphasis added). At that time, Applied agreed. JA28932 ("In that regard, [Applied] does not disagree with [Tyco].").

2. Applied's Expert Testified that Rigid Levers Operate Differently Than Flexible Fingers

Applied's technical expert Dr. Miller testified that rigid lever-like fingers function differently than flexible fingers. In his noninfringement opinion for the Smith '377 patent, he testified that rigid fingers and flexible fingers are completely different.[2] This testimony is directly relevant to the disputed claim construction issue regarding the Green '143 patent. According to Dr. Miller, flexible fingers do not "serve as sufficient mechanical levers to help dilate the valve opening." JA11169:10-12. On the other hand, rigid lever-like fingers function like a shoehorn, providing a much greater "mechanical advantage." JA11169:16-25. Thus, Applied's expert agreed that lever-like fingers provide a mechanical advantage because they concentrate and focus the enlarging force, whereas flexible fingers distribute any expansive force evenly over the inner wall of the seal.

[2] Although Dr. Miller testified that rigid fingers function differently than flexible fingers, he agreed that the fingers in Applied's trocars met the structural limitation at issue in claim 6 of the Smith '377 patent—i.e., guard members having end portions that are substantially more flexible than the remaining portions. Dr. Miller only disputed whether the end portions caused a reduction in insertion force, but the jury found differently. *See supra* Section III.C.3, at 16.

3. The District Court's Claim Construction

In the first trial, in addition to asserting the Smith '377 patent (the subject of Applied's appeal), Tyco also accused Applied's trocars of infringing claims 12 and 13 of the Green '143 patent. Claim 12 recites a valve assembly for inserting an elongated object into a patient's body that includes a "valve body member," a "first valve member," a "second valve member," and a "means engageable with the elongated object":

> d) means engageable with the elongated object upon insertion thereof into said proximal inlet opening of said valve body member, and adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein.

JA185 at 9:55-60. The parties agreed that "means engageable" is a means-plus-function limitation and that the function is facilitating the expansion of the valve aperture. The parties disputed, however, the structure that performed this function. The constructions proposed to the district court were:

Tyco's Construction	"a flexible strip of plastic that can conform to the inner wall of the valve member," JA5690.
Applied's Construction	"elongated pieces of flexible fabric," JA5797.

The district court recognized the dispute to be "whether the specification requires that 'fingers 78' must be flexible enough to conform to the inner wall of

the valve member in order to perform their claimed functions." JA47. While the court acknowledged that the specification describes the fingers as sufficiently flexible to conform to the shape of the inner wall, it said that the specification discloses that they "also" assisted in spreading the inner wall to facilitate expansion of the aperture. JA49-50. Reading these functions as mutually exclusive, the court said that the "specification does not clearly link or associate the 'conforming' element to the expansion of the aperture." JA50. The court declined to construe the corresponding structure of the "means engageable" limitation to be "a flexible strip of plastic that can conform to the inner wall of the valve member," and instead held it to be, simply, "fingers 78 and equivalents thereof." *Id.*

4. At the First Trial, Applied Presented No Evidence that the Structural Characteristics of the "Means Engageable" Limitation Are in the Prior Art

During the first trial, Applied stipulated to infringement of the Green '143 patent. JA8851. Accordingly, the parties tried the issue of whether claims 12 and 13 of the Green '143 patent are invalid for obviousness.[3]

To show that the "means engageable" limitation would have been obvious, Applied's technical expert Dr. Wolff Kirsch relied on two patents that he said

[3] The parties also tried infringement of the Smith '377 patent.

showed finger-like structures: 5,395,342 ("Yoon") and 2,328,948 ("Bourke").[4] Dr. Kirsch testified that claims 12 and 13 would have been obvious because each of the individual limitations, including "fingers," was separately known in the prior art. JA10935:9-16 ("Because all of the features in the ['143 patent] were already patented, were already commonplace, were already out there."). Specifically, as it concerned the "means engageable" limitation, Dr. Kirsch's testimony below is exemplary.

> Q: Was it already known in the field of valve assemblies to use legs or fingers to open up or protect valve openings?
>
> A: Yes.

JA10915:19-22.

> Q: [W]hat did the court say is – in its claim construction is the structure referred to . . . ?
>
> A: Well, that's a means issue. In other words, why, the mechanism, what's responsible for doing this. And it's equivalent. It's equivalent to what Yoon is doing, and it's equivalent to what Green is doing.

JA10920:15-21.

> Q: And, so, the structure that this court has said corresponds with limitation (d) is "fingers 78" from . . . the Green patent. So, even the word "fingers" for opening

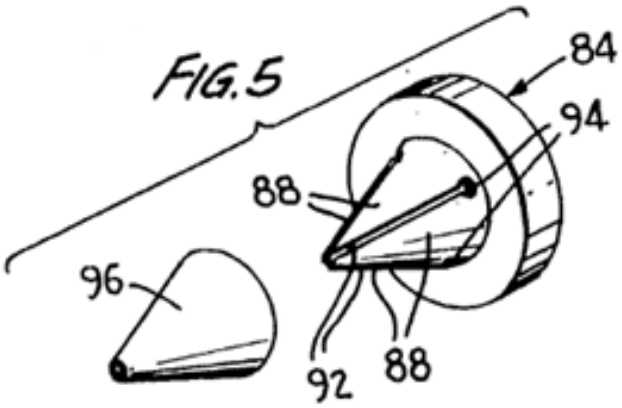
[4] Applied also relied on U.S. Patent No. 4,655,752 to Honkanen for obviousness, but that reference does not teach or disclose the use of guard members. JA26047-53; JA11127:20-24; JA11128:24-JA11129:21.

> up an orifice hole was well-known in the art, as shown by the Bourke patent. Is that not right?
>
> A: Yes.

JA10921:3-11.

Dr. Kirsch did not provide evidence or testimony that Yoon or Bourke have the same structure as described in the Green ’143 patent. Dr. Kirsch testified only that the fingers in Yoon and Bourke did the same thing, i.e., shared the same function. JA10908:13-17; JA10911:15-17; JA10914:7-12; JA10915:19-22; JA10921:8-11. And while Dr. Kirsch stated the legs in Yoon “are equivalent to fingers in the other patent” (JA10911:15-17), meaning the ’143 patent, he did not support or explain that assertion. Moreover, Dr. Kirsch did not present any evidence or opinion that any of the prior art “fingers” were sufficiently flexible to conform to the inner wall of the valve member.

None of the structures disclosed in Yoon or Bourke shares the same structural characteristics as “fingers 78” from the ’143 patent. None is sufficiently flexible to conform to the inner wall of the valve member. Figure 5 from Yoon (below) shows Yoon’s “legs 88”:



Although Yoon describes legs 88 as being "flexible," Yoon's legs are rigid legs that pivot, i.e., "flex," at relief recesses 94 at the proximal edge where they connect to body 84. *See* JA26040 at 5:43-50. Applied's expert, Dr. Kirsch, agreed that Yoon's legs were rigid and were able to withstand the constrictive force of the elastic sleeve 96. Specifically, he testified that "legs 88 have to have a certain degree of rigidity so they don't collapse when the sleeve [96] is put on." JA11032:6-10. Thus, Yoon's rigid legs operate like levers, pivoting at the "relief recesses 94." JA26040 at 5:43-50. The fingers of the claimed "means engageable" are more flexible than the rigid levers described in Yoon. But because of the district court's claim construction, the jury was able to disregard this important distinction between claims 12 and 13 of the '143 patent and Yoon.

The Bourke reference (JA26042-46), a nonanalogous patent from the early 1940s on beer kegs, also does not teach flexible fingers. Bourke, like Yoon, only discloses rigid finger-like levers, as opposed to the flexible fingers described in the '143 patent. Figure 2 from Bourke (below) shows Bourke's "fingers 27":

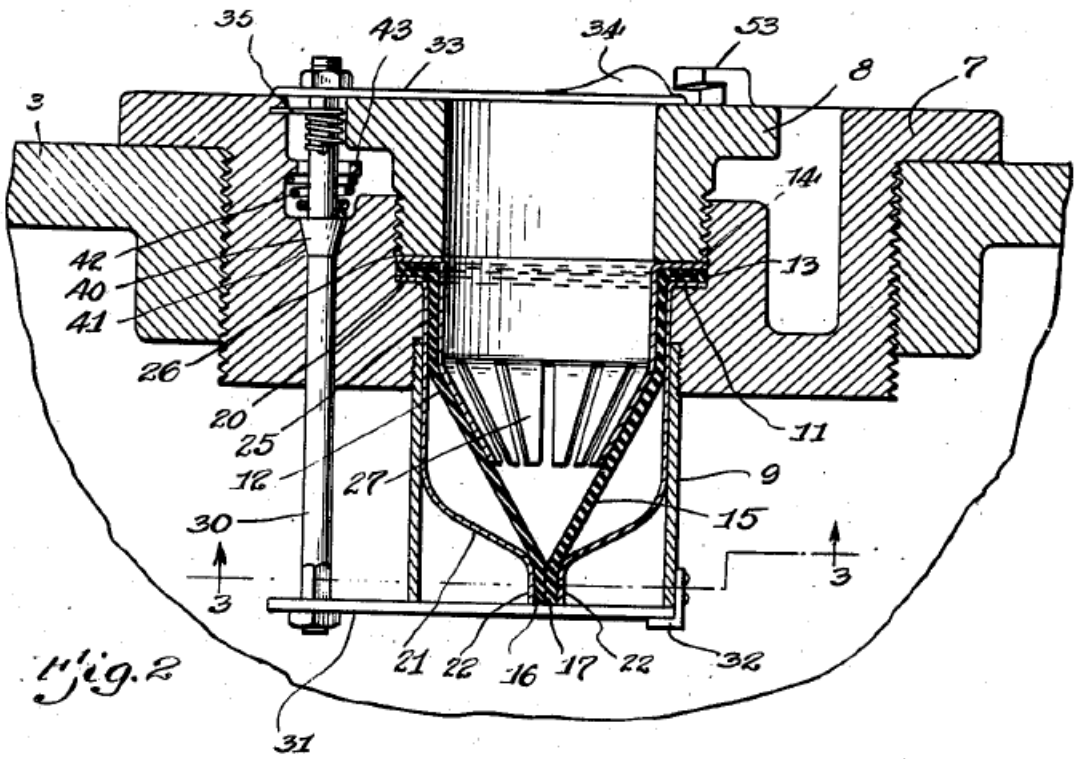


Fig. 2

As with the Yoon reference, no one testified that Bourke's "fingers 27" are sufficiently flexible to conform to the inner wall of a valve body or are an equivalent structure. Indeed, Bourke's "fingers 27" were characterized as "little shoehorn devices." JA10918:10-12; JA11169:16-21.

After trial, the jury found claims 12 and 13 of the Green '143 patent invalid based on obviousness. JA74.

5. The District Court Granted Summary Judgment of Invalidity of the Green Patents Based on Collateral Estoppel

The district court's erroneous claim construction in the first trial affected Tyco's second trial against Applied's next-generation trocars. Tyco asserted

additional claims from the Green patents that had not been tried in the first trial—claims 14 and 31 of the Green '143 patent and claim 4 of the Green '854 patent.

Applied moved for summary judgment of invalidity, contending that Tyco was collaterally estopped from asserting claims 14 and 31 of the '143 patent and claim 4 of the '854 patent based on the jury's finding from the first trial that claims 12 and 13 of the '143 patent were invalid for obviousness. JA14318-52. Applied provided no declaration in support of its motion. Tyco opposed and included a supporting declaration of its technical expert, who explained that the nonlitigated claims had a substantially different scope than the litigated claims. JA14605-36; JA14638-52. One week before the second trial began, the district court granted Applied's motion, precluding Tyco from asserting the Green patents against Applied's next-generation products. JA120-21. Two years later, the district court provided its rationale in a memorandum opinion. JA122-30.

B. The Second Trial

1. The Smith '702 and '377 Patents

In the second trial, Tyco asserted claims 1 and 5 of the Smith '702 patent and claims 1 and 2 of the Smith '377 patent. Like the Smith '377 patent, the Smith '702 patent (which is the parent of the Smith '377 patent) concerns a trocar with one valve member and a plurality of finger-like "guard members" adapted to expand the aperture of that valve member. The guard members described and

claimed in the Smith ’702 patent have at least two portions of differing rigidities. As before, the disputed limitation concerns the guard members, or “fingers.” With the relevant limitations emphasized, claim 1 of the ’702 patent recites:

> 1. Valve assembly for sealed reception of an elongated object, which comprises:
>
> a) valve body having at least one opening configured and dimensioned to permit entry of an elongated object and defining a central longitudinal axis;
>
> b) an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body, the aperture being configured and dimensioned such that insertion of the object into the aperture causes the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner; and
>
> c) a plurality of elongated guard members disposed within the seal member in contact with the inner surface thereof, the guard members positioned to engage the elongated object upon at least partial insertion of the elongated object into the valve body, *each of the guard members including at least a first substantially rigid portion and a second portion having less rigidity than the first portion*, each guard member adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member upon entry of the object therein.

Claim 1 of the Smith ’377 patent contains the same limitation. Although the specification describes an embodiment for providing differing rigidities—forming the guard members having portions of differing thicknesses (JA171 at 7:14-52)—

the asserted claims are not so limited and claim differing "rigidities," not differing "thicknesses." None of the asserted Smith claims is in means-plus-function form.

Figures 5 and 8A of the Smith '702 patent are shown below and depict, among other limitations, an embodiment of the claimed guard members with differing rigidities. JA158 (Fig. 5); JA160 (Fig. 8A).

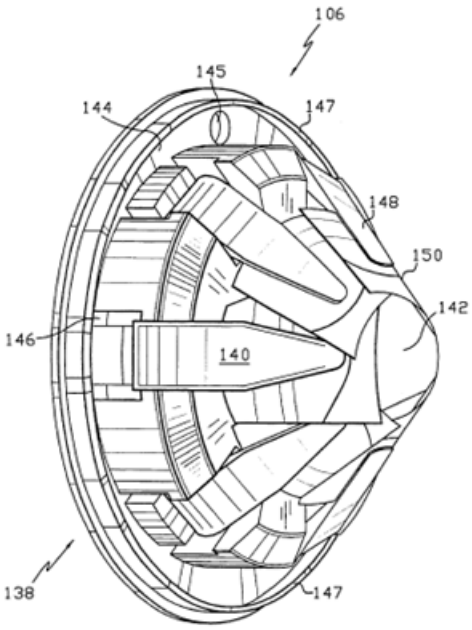


FIG.5

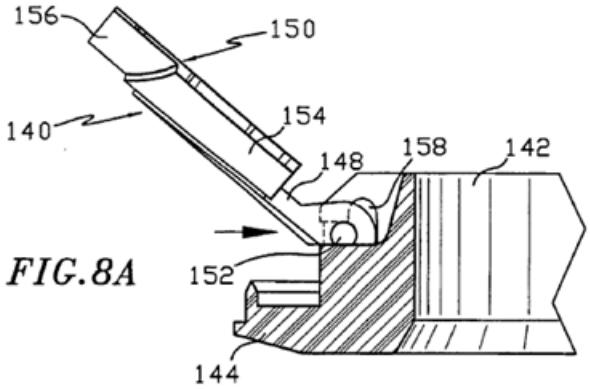


FIG.8A

Figures 5 and 8A illustrate the claimed guard element 140 having a first portion 154 and a second portion 156 of varying rigidities. The first portion is more rigid than the second because, in that embodiment, "[t]he first or proximal portion 154 has a cross-sectional dimension or thickness which is greater than the thickness of the second or distal portion 156 of the outer flap 150." JA171 at 7:15-20.

2. The District Court Refused to Construe a Disputed Limitation

After the first trial, the district court said that "it is difficult to imagine that the [newly accused] products are so different from those first [accused] that different claim terms would need to be construed, and another round of claim construction need be done." JA15527. Notwithstanding its reluctance to construe any additional terms, the court permitted the parties to brief any remaining issues for claim construction. JA15528.

The parties disputed the claim limitation concerning differing rigidities. JA15599-611; JA16836-37. Tyco predicted that relying on the plain meaning of the disputed terms would "not sufficiently protect Plaintiffs" because Applied "would add limitations into the claims that are inconsistent with the specification and the context provided by the other claims." JA15603; JA18292. For example, dependent claim 4 of the '702 patent (not asserted) further limits the guard members such that the differing rigidities are provided by differing thicknesses:

> 4. The valve assembly according to claim 1 wherein the first portion of each guard member defines a cross-sectional dimension which is greater than the cross-sectional dimension of the second portion of the guard member.

JA173 at 12:57-60. Dependent claim 4 shows that independent claim 1 encompasses other ways to provide for dual-rigidity fingers without simply

varying the thickness. *Id.* Accordingly, Tyco proposed the following constructions:

Term	**Tyco's Proposed Construction**
a first substantially rigid portion	a region that is sufficiently rigid to assist expansion of the aperture of the seal member
a second portion having less rigidity than the first portion	another region that has less rigidity, i.e. more flexibility, then the first to enhance passage of the elongated object through the valve body

JA18296. Rather than resolve the parties' dispute and construe the disputed limitation, the district court concluded that "the parties' squabble is not about claim scope" and ruled that the terms would be given their plain and ordinary meaning. JA113 n.1.

3. Applied Offered Its Own Construction at Trial

During trial, Applied's counsel sought to place its spin on the "plain and ordinary meaning" of the disputed terms by arguing to the jury that differing rigidities, in the context of the Smith patents, means differing thicknesses, i.e., "dual thickness." In his opening statement, Applied's counsel said that the parties "have a real dispute as to what [Tyco] think[s] the Smith patent is all about." JA23271:12-19. According to Applied's counsel, the Smith patents are about guard members having different thicknesses, which was known in the art. JA23290:21-JA23291:11. Applied argued that its trocars do not infringe because the guard members of the accused products have uniform thickness. JA23297:23-

JA23298:1. Moreover, because their trocars have folding guard members, rather than pivoting guard members, Applied argued that they cannot infringe since "nowhere in the patent is there any discussion or contemplat[ion of] folding anything." JA23293:8-10.

Applied's counsel and its technical experts continued to make similar claim-construction arguments throughout trial. Despite the district court's "plain and ordinary meaning" construction, Applied's counsel argued to the jury that, in the context of the Smith patents, differing rigidities were accomplished by using differing thicknesses and *only* differing thicknesses. At each instance, Tyco's counsel objected, and the court repeatedly cautioned Applied not to run afoul of the court's plain-meaning construction. *See, e.g.*, JA23555:6-10; JA23557:5-12; JA23558:24-JA23559:8; JA23564:21-JA23565:2; JA23572:18-JA23574:12; JA23576:23-JA23577:8; JA23582:25-JA23586:25; JA23597:3-JA23599:2; JA23605:24-JA23606:15; JA23610:14-JA23611:1; JA24449:18-JA24450:14; JA24454:14-JA24455:11; JA24740:23-JA24741:14; JA25058:8-JA25060:10.

Below are exemplary excerpts of Applied's claim-construction arguments made through its technical expert, Dr. Miller:

> Q: Now, how does the patent explain why callout 156 would have less rigidity than callout 154?
>
> A: It's thinner. That's how it has less rigidity.

JA25047:10-12.

> Q: And wasn't it clear to you, from listening to [a co-inventor] that the way to vary rigidity was varying the thickness?
>
> A: Yes. That's exactly what his intent was.
>
> Q: And is there anything in the patent, in the patent, that suggests any other way to vary the rigidity of a guard member?
>
> A: No. I understand from reading the –
>
> [Tyco's counsel objects, the district court sustains and instructs the jury to compare the claims to the accused device to determine infringement]
>
> Q: Do the claims in this case—do the claims in any way suggest or claim the idea of varying rigidity by folding?
>
> A: It just states in the asserted claims that there is a section that has less rigidity than a substantially rigid portion.
>
> Q: Would anybody of skill in the art, such as yourself, read the claim and think the claim is directed to folding objects?
>
> [Tyco's counsel objects]

JA25048:2-JA25049:14.

The district court then conducted a sixteen-minute discussion with counsel outside the presence of the jury on whether it should provide a construction for "substantially rigid" or otherwise grant a mistrial. JA25049:17-JA25062:23. The court characterized the issue as "whether or not when I define something in the plain and ordinary meaning [whether] this witness can go back and go through the

Smith patent and come up with what he feels as a person of ordinary skill in the art after looking at this says that's the ordinary meaning." JA25054:7-19. After receiving unsatisfactory answers from Applied's counsel, the court decided that in light of the preceding events, it would construe the claim and deny Tyco's motion for mistrial:

> COURT: Okay. What I'll do is I'll construe the claim.
>
> TYCO'S COUNSEL: I think we have to construe "substantially rigid," your Honor.
>
> COURT: Okay.
>
> TYCO'S COUNSEL: I think we have to at this point because it's a mistrial otherwise.
>
> COURT: Okay. . . . I'm going to resolve this issue by construing this claim. I think that the jury deserves that. Any motion for a mistrial is denied.

JA25060:4-25.

Notwithstanding these statements, the district court never provided a construction for the "substantially rigid" limitation other than its "plain and ordinary meaning." JA118-19. Thus, the jury was left to determine the construction of the disputed limitation on its own. *See*, *e.g.*, JA25080:3-13 (Applied's expert opining that the accused device does not have "first and second portions of differing rigidity" because "[t]he pleated skirt is one unitary, the same thickness and the same material," "[i]t's all uniform throughout," and "[i]t's the

same thickness"). When pleading with the court for additional time to present its defense, having spent so much time presenting claim-construction arguments to the jury, Applied's counsel even admitted "that the specification and the claim construction issue is what has sidetracked this trial." JA25162:24-JA25163:4.

In his closing argument, Applied's counsel continued to make claim-construction arguments, even telling the jury it was their job to decide what the invention was:

> But I was angry throughout this trial because we didn't have agreement on what the invention was.

JA25690:24-25.

> We had disagreement on what the patent was really about. That's why we had so many sidebars.

JA25693:2-4.

> Now, I said the disagreement with the other side is we don't know what the invention is.

JA25706:6-7.

> I want to teach you a little patent law. I've got to. I have to. [Tyco] made the analogy to a fruit salad, and [Tyco] said if I show fruit salad and I put in my patent . . . strawberry, bananas, . . . berries and they claim fruit – yes, they're entitled to claim fruit generally. I agree with that, because these are all consistently fruit.
>
> But what I have a problem with is saying [Tyco] invented the salad, with nuts in it and [Tyco] invented a nut salad. That, I've got a problem. And that analogy is because in all the fruit in the patent, it's always a variation in

> thickness. There is no other way to vary rigidity other than changing the cross-sectional area unless you change the material—I don't know why you'd want to do that. But there's no other way, and there's nothing in the patent or contemplated by anybody about folding. . . .
>
> [Applied's counsel played a snippet of the inventor's deposition]
>
> Any doubt what the invention was in Mr. Smith's mind? Changing the thickness. . . . This is a pretty simple case. It's about thickness.

JA25709:11-JA25711:23.

> Now we know what the invention is. . . . It really requires dual thickness.

JA25713:21-24; JA25714:23-25.

> Could it be that Tyco is now making Mr. Smith's invention out to be something he never really intended?

JA25737:7-9.

> I'm also really curious how Tyco has any explanation for how all these prior art guards with different shapes, different geometries, different thicknesses are somehow different than the Smith invention but at the same time, same time, Applied's pleated skirt which is in the other neighborhood, with uniform thickness, uniform curvature, somehow that's the same as the Smith invention.

JA25737:20-JA25738:2.

In its jury charge, the district court did not give a construction for the dual-rigidity limitation. *See* JA25561; JA25594.

4. Applied's Dual-Thickness Arguments Impacted Infringement and Validity

During trial, Applied's focus on the Smith patent claims requiring guard members having a dual thickness rather than dual rigidities impacted both infringement and validity. Tyco presented evidence that, although the guard members in Applied's trocars have uniform thickness, their geometry and structural arrangement caused them to have differing rigidities.

Applied's trocars at issue in the second trial have a Ws septum shield, which includes an elongated pleated structure that forms a starburst pattern as shown below.

Tyco's expert Dr. John Collins testified that these guard members have differing rigidities—they are substantially rigid at the outer ridge and less rigid on the inside. *See, e.g.*, JA23479:6-JA23483:11; JA23490:2-JA23492:7. Dr. Collins presented the results of different tests showing the differing rigidities of the guard members. *See, e.g.*, JA23493:8-JA23494:20; JA23496:2-JA23505:4; JA30102-13. Applied, on the other hand, conducted no tests to show that the guard members have different rigidities instead arguing that the claims require differing thicknesses. *See, e.g.*, JA24834:9-JA24836:3; JA24875:6-JA24876:22; JA25195:21-25; JA25221:10-JA25222:10. Because of Applied's claim-construction arguments, the jury was able to ignore Tyco's evidence establishing dual rigidities of the guard members and focus on their thickness.

Likewise, Applied's dual-thickness arguments allowed the jury to ignore the evidence showing that the prior art does not disclose guard members with differing rigidities. In his closing, Applied's counsel emphasized to the jury that Applied "picked one patent to really explain that this patent is invalid, Rowe" (JA25726:3-4), referencing U.S. Patent No. 5,342,315 (JA26143-77). And Applied's counsel argued: "And is there any doubt there's dual thickness in this? Any doubt? No doubt whatsoever." JA25726:9-10. Likewise, referring to Rowe figures 50, 52, and 58, Applied's expert testified that alleged guard member 962 "has a different thickness," pointing to a "bump" in the member. JA25103:9-24; JA25727:3-11

(counsel arguing that Applied was referring to element 962 in Rowe); *see also* JA25105:4-25.

On the other hand, Covidien's expert, Dr. Collins, one of the inventors of the Rowe patent, focused on whether Rowe discloses guard members having a substantially rigid portion and a portion with less rigidity, and testified that it does not. *See, e.g.*, JA25379:12-JA25382:23. And the Rowe patent likewise does not describe the alleged guard members, including guard member 962, as having differing rigidities. JA26170-75.

V. SUMMARY OF THE ARGUMENTS

A. Applied's Appeal

Applied raises two issues in its appeal, each concerning the Smith '377 patent: (1) the district court's construction of "minimize," and (2) whether substantial evidence supports the jury's finding of infringement.

The district court's construction of "minimize" to mean "reduce" is supported by the plain language of the claim, the specification, and extrinsic evidence. The claim tempers the word "minimize" with the adverb "effectively." According to the specification, an effective reduction in force is achieved by using guard members with end portions that are about two to three times more flexible than the base portions. Nothing in the intrinsic record requires a reduction in insertion force to be an absolute extreme, i.e., the minimum under the

circumstances. Moreover, common usage of the word "minimize" as established by contemporaneous dictionaries is consistent with a general reduction, rather than an absolute reduction to the lowest level possible under the circumstances. This Court should affirm the district court's construction of "minimize."

The jury's finding of infringement is supported by substantial evidence. Applied does not dispute that the guard members in its accused trocars satisfy the dual-rigidity limitation and reduce insertion forces. Applied's documents confirm that its trocars require less insertion force than its prior designs. Applied only disputes whether this reduction in insertion force was caused by the flexibility in the guard members' end portions as opposed to the guard members as a whole. On this point, the jury heard the testimony from Applied's expert and Tyco's expert, assessed credibility, and found Applied liable for infringement. This Court should affirm the district court's denial of Applied's motion for judgment as a matter of law on the issue of infringement.

B. Tyco's Cross-Appeal

Tyco raises two claim-construction issues on appeal. The first involves the district court's broad construction of a means-plus-function limitation in the Green patents. The second stems from the court's failure to construe a disputed term in the Smith patents and to prevent Applied from making claim construction arguments to the jury.

Regarding the first claim construction issue, the Green ’143 patent describes a single embodiment of a dual-valve trocar having flexible fingers that conform to the inner wall of the elastic valve member. The flexible fingers are claimed in means-plus-function form. But the district court’s construction did not limit the means-plus-function element to the structure disclosed in the specification. The court incorrectly found that the ’143 specification did not link the structural requirement that the fingers conform to the inner wall of the valve to the function of facilitating expansion of the aperture. The court’s construction also ignored the portions of the intrinsic record that distinguished rigid, finger-like levers (known in the prior art) from the claimed, flexible fingers that conform to the inner wall of the elastic valve to distribute the spreading forces more evenly across the valve member. The district court’s construction should be modified as Tyco proposed in its construction.

The second claim construction issue relates to the Smith patents, which claim a trocar having guard members with portions of at least two different rigidities. Despite that the parties had a dispute about the scope of the dual-rigidity limitations, the district court would not construe them and held that the plain and ordinary meaning applied. Applied’s repeated arguments to the jury that the dual-rigidity limitations were limited to dual thickness, showed that there was a genuine dispute about their scope. Tyco’s objected repeatedly to Applied’s impermissible

claim construction arguments made to the jury and each time the district court agreed with Tyco. The court went so far as to deny Tyco's motion for mistrial and agree to construe the claim for the jury—but the court later changed its mind (over Tyco's objection) to prevent recalling some experts to testify again under a new construction. By refusing to construe the limitations, the district court improperly left claim construction to the jury. The jury's verdict in the second trial should be vacated and the case remanded under a proper construction of the dual-rigidity limitations.

VI. ARGUMENT FOR APPLIED'S APPEAL

A. Standard of Review

A district court's claim construction is reviewed *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (en banc).[5]

This Court reviews denials of JMOL *de novo*. *i4i Ltd. v. Microsoft Corp.*, 598 F.3d 831, 841 (Fed. Cir. 2010). "JMOL is appropriate only if the court finds that a 'reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Id*. (quoting Fed. R. Civ. P. 50(a)(1)) (applying 5th Circuit law). The Fifth Circuit is "'wary of upsetting jury verdicts' and will 'uphold a jury verdict unless the facts and inferences point so strongly and so

[5] *But see Lighting Ballast Control LLC v. Philips Elecs. N.A.*, Nos. 2012-1014, -1015 (Fed. Cir. Mar. 15, 2013).

overwhelmingly in favor of one party that reasonable jurors could not arrive at any verdict to the contrary.'" *Goodner v. Hyundai Motor Co.*, 650 F.3d 1034, 1039 (5th Cir. 2011) (citations omitted); *see also Boeing Co. v. Shipman*, 411 F.2d 365, 375 & n.16 (5th Cir. 1969) (en banc) (stating that JMOL motions "should not be decided by which side has the better of the case," as the resolution of that question resides with the "jury as the traditional finder of the facts, and not the Court, to weigh conflicting evidence and inferences, and determine the credibility of witnesses").

B. The District Court's Construction of "Minimize" Is Correct

Applied argues that the term "minimize" should be construed to mean "reduce . . . to the minimum level possible under the circumstances," rather than "reduce." Applied Br. at 29. The district court's construction of "minimize," however, is consistent with the plain language of the claim, the specification, and extrinsic evidence.

1. The Plain Language of the Claim Supports the District Court's Construction

Applied relies primarily on dictionary definitions and claim constructions in unrelated contexts to construe the otherwise plain and ordinary meaning of the verb "minimize." *Id.* at 29-32. Applied ignores, however, the adverb in the claim that further modifies minimize—"effectively." The ordinary meaning of "effectively" is "in a way that produces a desired result; in an effective manner; in

an indirect way." *Merriam-Webster.com* (available at http://www.merriam-webster.com/dictionary/effectively). Thus, when read together, "effectively minimize" tempers the extreme construction sought by Applied. These words only require minimization sufficient to achieve a desired result, i.e., a reduction sufficient to achieve a desired result. Indeed, Applied itself proposed that minimize means "reduce"—it just disputes the extent of the reduction. The adverb "effectively," both from the claim language and in the court's construction, resolves that dispute.

2. The Specification Supports the District Court's Construction

The Smith '377 specification explains that, by designing the end portions of the guard members to be "*about* two to three times more flexible" than the proximal portions, the claimed trocar "provide[s] *sufficient flexibility* to minimize the force required to advance the instrument through the guard element and seal arrangement." JA149 at 7:17-34 (emphases added). Nothing in the specification requires the end portions of the guard members to have a specific amount of flexibility nor is there anything that requires the reduction in force be to the "minimum level possible under the circumstances."

Notwithstanding, Applied relies on the same part of the specification to argue that the insertion force must be reduced to the "minimum level possible" simply because the excerpt contains the word "minimize." Applied Br. at 30-31.

This part of the specification, when read in context, however, describes a *general* reduction in insertion force, rather than an *absolute* reduction, as the object of the invention. The specification describes the difference in flexibility between the end portion and the proximal portion of the guard members using a broad range (about two to three times), rather than a specific difference in flexibility. JA149 at 7:15-53. Thus, the specification teaches that a difference in flexibility of about two to three times between the end portions and proximal portions of the guard members is "sufficient" to achieve the desired result. *See id*. This is further supported by the claim language that only requires the force to be "effectively" minimized. *See supra* Section III.A, at 6.

The district court's construction of "effectively minimize," requiring only an effective reduction rather than to an absolute minimum, is also consistent with the specification's "Summary of the Invention." Here, the specification describes the thinned tips of the guard members as "reduc[ing] the forces required to advance the elongated object through the valve housing." JA147 at 3:58-52. It does not describe a reduction of force to the "minimum level possible."

Other portions of the specification are in accord. The guard members are described as dimensioned such that the thicker portions are used to stretch the valve open while "the *relatively* thin and *less* rigid, second portion 156 of outer flap 150 *reduces* the force required to pass the instrument through the guard mount

and seal arrangement." JA149 at 7:34-45 (emphasis added). In other words, "the particular dimensioning of the guard elements 140, i.e., the rigid section in combination with the more flexible outer portion, ensures *adequate* stretching of the seal element 110 while also permitting *relatively easy* passage of instrument 400 through the valve assembly." JA150 at 10:44-49 (emphases added). The benefits of the invention are described in general terms—by making the ends of the guard members more flexible, a trocar designer can effect a reduction in insertion force.

3. Applied's Dictionary Definition Does Not Require a Different Construction

Applied primarily relies on a dictionary definition to argue that "minimize" should be construed to mean to reduce to the minimum level possible. Applied Br. at 29-30. But, as discussed above, neither the claims nor the specification use minimize to mean reduce to the minimum level possible. Moreover, other modern dictionaries define "minimize" to mean simply "to reduce." *See, e.g.*, American Heritage College Dictionary (3d ed. 2000); American Heritage College Dictionary (4th ed. 2001).[6] These more modern definitions are consistent with the

[6] According to traditional grammar, minimize means "to make as small as possible." American Heritage Dictionary (2d College ed. 1991). The newer use of minimize, however, is "to make smaller than before," *id.*, which was well established by the time the application for the '377 patent was filed.

specification and claim language, and support the district court's construction of "minimize" to mean "reduce."

4. Alternatively, the Court Should Adopt Tyco's Proposed Construction of "Effectively Minimize" to Mean "Sufficiently Reduce"

Tyco's proposed construction of "effectively minimize" was "sufficiently reduce." JA1543; JA33. "Sufficiently" means enough to meet the needs of a situation and is a synonym of "effectively." *See Merriam-Webster.com* (available at http://www.merriam-webster.com/thesaurus/sufficiently) (defining sufficiently and indicating that it is related to effectively). Further, "sufficient" is used in the Smith '377 patent specification to describe the difference in flexibility between the end and base portions of the guard members to effect the reduction in insertion force: "Such dimensioning of outer flap 150 ensures that guard elements 140 . . . provide *sufficient* flexibility to minimize the force required to advance the instrument through the guard element and seal arrangement." JA149 at 7:17-34 (emphasis added). Such a construction, if adopted, would not have changed the result for the reasons articulated above. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328-29 (Fed. Cir. 2002) (holding that even in view of an erroneous claim construction, a reversal is only available when that error would have changed the result).

C. Substantial Evidence Supports the Jury's Finding of Infringement

Applied does not dispute that its accused trocars meet the structural limitations of claim 6 of the Smith '377 patent. Nor does Applied dispute that "the end portions of the guard members [in its trocars] are substantially flexible relative to the remaining portions of the guard members" or that the guard members as a whole reduce the insertion force on an elongated object advanced through them. Applied Br. at 32-33, 40-41. Applied only disputes whether substantial evidence shows that the reduced insertion force is caused by the more flexible ends of the guard members to meet the functional limitation of "effectively minimiz[ing] force required to advance the elongated object through the guard members." *Id.*

On appeal, Applied contends that evidence that the guard members reduce insertion force is "not evidence of infringement" and is "not probative of infringement." Applied Br. 40. But evidence that the guard members reduce insertion force is evidence that makes it more likely than not that the accused products infringe. *See Lucent Tech. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009) (holding that the jury is permitted to find infringement more likely than not based on circumstantial evidence). The jury heard testimony that Applied's "leaflets" with thinned ends achieved reduced insertion forces. JA10721:8-12 (Applied's witness, Gary Johnson, testifying that "a feature of the new septum shield with the leaflets, with the thinner ends, is that it reduces the friction when

putting [in place or] withdrawing instruments from the seal"). The jury could reasonably conclude from this evidence that the more flexible ends of the guard member leaflets in Applied's trocars led to the reduced insertion forces, particularly when that is coupled with the testimony of Tyco's expert and other witnesses.

Specifically, Tyco's expert, Mr. Dubrul, attributed the reduced insertion force to the more flexible ends of the guard members. JA11553:4-JA11559:9. He testified that thinner end portions of the guard members are more flexible at the end and would reduce the amount of force necessary to insert instruments through the valve. JA11557:17-23; JA11576:3-JA11577:5. He explained that thinner material is easier to get through than thicker material. JA11576:9-17. And Applied witnesses testified similarly. JA10872:25-JA10873:18; JA11210:4-18. Neither party challenged, through a *Daubert* motion, the methodology used by the opposing expert. Similarly, neither party sought to exclude, through a motion in limine, the testimony of the opposing expert as irrelevant, prejudicial, or on some other evidentiary ground. Instead, both experts testified and defended their positions while the jury listened, observed, and rendered its verdict.

1. This Court Should Not Second-Guess the Jury's Verdict

Applied's argument, when distilled, is that no reasonable juror could have disbelieved the testimony of its experts. As this Court has stated in response to

similar arguments: "This is plainly incorrect. It is not the province of an appellate court to second guess the jury's credibility determinations or to reevaluate the weight to be given the evidence." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1192 (Fed. Cir. 1998). "It is within the province of the jury to determine the credibility of a witness and the weight to be given his testimony; the jury is not required to accept testimony as true, even if it is uncontradicted." *Amsted Indus., Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 183 (Fed. Cir. 1994). The jury simply found Tyco's expert was credible and Applied's experts were not.

2. Tyco Presented Substantial Evidence of Infringement

The jury in this case heard extensive evidence on infringement. That evidence included the testimony of Tyco's expert, Mr. Dubrul. He explained the evolution of Applied's trocars from one without any guard members to ones with guard members having flexible ends—the accused products. Mr. Dubrul showed the jury Applied's testing, sales-training manuals, and marketing materials that describe reducing the insertion force required to pass an instrument through the trocar as a benefit of the accused trocars. Mr. Dubrul discussed each of the following exhibits:

- **Applied's Patent Application** (PTX21): Applied's patent application disclosed a device that would "reduce[] the drag force encountered when placing or removing instruments through the seal" and disclosed fingers having end portions that are more flexible than

the remaining portions. JA28566; JA28567-68; JA28581. Applied admitted that this was its attempt to patent the accused products. JA10865:1-JA10867:25.

- **Marketing Document** (PTX395): This document focuses on the accused products and specifies that the new seal design "reduces instrument drag" and "minimizes drag for enhanced instrument control." JA28766-67. Gary Johnson (from Applied) testified that the device discussed in this document has guard members with thinner ends. JA10727:3-JA10728:5.

- **Johnson's Email** (PTX237): This email discusses a trocar design by an Applied engineer who implemented guard members similar to those found in the accused products (JA10613:11-JA10615:5), and Mr. Johnson, another Applied engineer, observed that this design "dramatically reduced the insertion force" (JA28734; JA10615:7-JA10616:11).[7]

- **Design-Verification Report** (PTX418): This report set forth the results of Applied's internal tests on a trocar having guard members with flexible ends. These tests established that the new trocar design "reduce[d] tool drag" during insertions and removals of the instruments. JA28860; JA28865; JA9986:11-JA9987:2.

Mr. Dubrul then explained to the jury, while holding the accused trocars and passing them around to the jury, how they worked and how they met each

[7] Applied asserts (without support) that the "guard member design" discussed in this email "did not have thinner end portions." Applied Br. at 40. But Applied's engineer Mr. Hart testified that this email concerned Applied's second-generation product. JA10614:4-JA10618:11. At trial, the second generation-product referred to the design that included guard members with thinned tips. JA10617:4-8 (first generation did not have fingers); JA10727:20-JA10728:5 (second generation has fingers with thinner ends). On redirect, Mr. Hart testified that the second generation product did not have thin tips at the time of this email. JA10633:20-JA10634:20. The jury heard this conflicting testimony and was able to judge his credibility and determine whether to believe his changed testimony.

limitation of claim 6. *See, e.g.*, JA9987:5-JA9989:12; JA10003:24-JA10004:18. He also explained how he tested the accused products (JA10016:11-JA10020:18), how his testing was relevant to infringement (JA10021:1-JA10023:25), and how his tests were still probative of infringement even though they were conducted without the elastomeric seal (JA10148:5-JA10151:17).

Applied tries to dismiss the undisputed point that it takes more force to push through something that is thicker than if it is thinner by arguing that the guard fingers are in contact with the elastomeric seal valve. Applied Br. at 39. But Mr. Dubrul testified that the elastomeric seal valve acts as a constant force against the guard members. JA10148:5-18; JA11576:3-17. He explained that it is easier to get through a thinner material next to a constant seal than a thicker material next to a constant seal. JA11576:3-17; JA11578:22-JA11579:11. All of this evidence supports the jury's verdict of infringement.

a. Mr. Dubrul's Testimony Is Consistent with the Court's Claim Construction

Applied argues that Mr. Dubrul's testimony is contrary to the claim language and district court's construction. Applied Br. at 33-36. This is incorrect. First, Applied only disputed the "effectively minimize" limitation. JA11193:5-9. Both the plain language of the claim and the Court's construction require reduced force when an instrument is passed through the "guard members." JA103. Tyco presented substantial evidence on this point.

After Mr. Dubrul testified, the district court clarified that, even though the claim requires a reduction of force through the "guard members" (as tested by Mr. Dubrul), the guard members had to be in contact with the elastomeric seal. Mr. Dubrul's testimony was consistent with this construction all along, because he expressly stated during Tyco's case-in-chief that his opinions regarding a reduced insertion force would be the same whether the fingers were in contact with the elastomeric seal or not. JA10148:5-JA10149:4.

When Mr. Dubrul took the stand again after the court modified its construction, he confirmed that the clarified construction did not change his opinion. JA11540:10-JA11541:13. He explained that the elastomeric seal would act as a constant force against the guard members and its presence or absence would not impact his conclusions one way or the other. JA11556:10-JA11559:9; JA11576:3-JA11577:14.

b. Substantial Evidence Established that the Accused Products "Effectively" Reduced Insertion Force

Applied contends that Tyco never presented evidence that the insertion force is "effectively" reduced. Applied Br. at 43-44. Applied suggests that Mr. Dubrul needed to quantify any reduction in insertion force (*id.* at 43), but neither the Smith '377 patent nor the district court's construction required this. Notwithstanding, Mr. Dubrul testified that the ends of the guard members on the accused products

were 60 percent more flexible than the thicker base (JA11553:4-22), that the elastomeric seal would act as a constant (JA11576:3-8), and that the guard members with flexible ends reduced the insertion force (JA11576:9-17).

After analyzing Applied's documents and its accused trocars, and conducting his tests, Mr. Dubrul testified that Applied's trocars "effectively" reduced the insertion force:

> Q: [T]hat floppier end portion is going to "effectively minimize the force required to advance the elongated object through the guard members," through that plastic piece you held up, right?
>
> A: Exactly.

JA10010:14-19; *see also* JA10010:20-JA10011:19.

> Q: Now let's talk about the last bit, "to effectively minimize force required to advance the elongated object through the guard members." Is that part of the claim met by the two accused products?
>
> A: Yes, sir, they are.

JA11547:14-18.

> [ON CROSS-EXAMINATION]
>
> Q: [I]t sounds like [it's] your opinion that Applied's thinner tips in their device actually do somehow effectively minimize or reduce the force required to advance an elongated object through the instrument, right?
>
> A: That last element as the court has construed, yes. Those two famil[ies] of products . . . do infringe that element as well as other elements.

. . . .

> Q: It's your view that the thinner tips effectively minimize the insertion force that's required to advance the elongated object through the instrument, right?
>
> A: Well, more specifically, as the court construed, "through the aperture."

JA11561:9-JA11562:25.

Applied's documents confirmed that its accused trocars dramatically reduced the insertion force. *See, e.g.*, JA28734 (PTX237) (email stating that the accused products "dramatically" reduced the insertion force); JA28766-67 (PTX395) (training manuals touting the reduced insertion force and "minimize[d] drag" made possible by the design of the accused products); JA9992:21-JA9995:4 (testimony concerning PTX395). Mr. Dubrul's testimony links this reduction in insertion force to the flexible ends of the guard members. *See, e.g.*, JA10010:14-JA10013:16.

The plain meaning of "effectively" is to achieve a desired result. Here, the result desired—a reduced insertion force—is achieved because the flexible ends of the guard members "reduce[d] the forces required to advance the elongated object through the valve housing." JA147 at 3:58-62. Mr. Dubrul's testimony, Applied's documents, and Applied's witnesses all support the jury's finding that Applied's trocars effectively reduced insertion force and therefore infringe claim 6 of the Smith '377 patent.

c. Applied's "Relevance" Attack on Mr. Dubrul's Testing Lacks Merit and Is Waived

Applied disagrees with Mr. Dubrul's testing method and with the conclusions he drew from that testing. Applied Br. at 33-36. A patentee may prove infringement, however, by "any method of analysis that is probative of the fact of infringement," *Forrest Labs. v. Abbott Labs.*, 239 F.3d 1305, 1312 (Fed. Cir. 2001), and circumstantial evidence may be sufficient, *Lucent*, 580 F.3d at 1318. Indeed, there is no "general rule requiring one who alleges infringement of a claim containing functional limitations to perform actual tests or experiments on the accused product or method." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1374 (Fed. Cir. 2009).

Mr. Dubrul, an expert in the field of trocar design, testified that Applied's accused trocars meet each limitation of claim 6, including the functional limitation that the flexible ends of the guard members effectively reduce insertion force. He based his opinion on Applied's documents, his analysis of the products, and tests on the guard members of those products. JA9966:18-JA9967:9. Mr. Dubrul explained that he had devised a testing protocol to assess the relative flexibility of the ends of the fingers in order to assess the difference in force required to bend the ends of the fingers rather than the base of the fingers. JA10016:25-JA10020:25. He further explained that the presence or absence of the seal would not change his

opinion.[8] This expert testimony, which was based on the infringing products, is substantial evidence of infringement. *Martek*, 579 F.3d at 1373-74 (holding that "expert testimony based on the accused [product] that supports a finding of infringement" was "substantial evidence supporting the jury's infringement verdict [and] the district court did not err when it denied [defendant]'s JMOL motion").

At most, Applied's challenge is to the relevancy of Mr. Dubrul's testing methodology and his opinions based, in part, on those tests. Applied waived any such challenge to the admissibility of that testimony, however, because it never filed a *Daubert* challenge or otherwise tried to exclude Mr. Dubrul's opinions through a motion in limine. *See Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1264 (Fed. Cir. 2013) (holding that challenges to an expert's methodology or the extent to which an expert's analysis are "properly tied to the facts of the case" "should be resolved under the framework of the Federal Rules of Evidence and through a challenge under *Daubert*").

In reality, Applied's challenge is simply a disagreement with Mr. Dubrul's expert opinion. The parties agreed that (a) Applied's trocars had guard members with more flexible ends, and (b) those products, as a whole, reduced insertion

[8] Mr. Dubrul had confidence in his opinion on this point because he had previously conducted tests showing this, even though the tests were not presented to the jury. *See supra* Section III.C.3, at 17 n.1.

force. JA11192:2-JA11193:11; JA10614:12-JA10616:2. The only issue then was whether (b) was caused by (a). Mr. Dubrul testified *yes*, with supporting documents and tests. Applied's expert, Dr. Miller, disagreed and testified *no*. The resolution of that issue—a battle of the experts—is left to the sound discretion of the jury. *Comark*, 156 F.3d at 1192 ("It is not the province of an appellate court to second guess the jury's credibility determinations or to reevaluate the weight to be given the evidence.").

3. The Jury Was Free to Discredit Applied's Testing and Other Arguments

Applied's expert, Dr. Miller, testified that he agreed with Mr. Dubrul that Applied's accused trocars meet every structural limitation of claim 6 and that his disagreement came down to a functional limitation. JA11193:5-12. More specifically, he gave his opinion that, while the structural limitations were met, the thinned portions of the guard members in the accused products did not cause the reduction in insertion force. JA11169:8-JA11170:5; JA11194:2-11. Relying on different tests by Dr. Hogan, Dr. Miller criticized Mr. Dubrul's tests as inconsistent with their intended clinical usage. JA11178:20-JA11179:20.

Dr. Hogan, on the other hand, admitted that his own tests were not conducted in a manner consistent with their intended clinical usage. JA11331:25-JA11332:15. Instead, Dr. Hogan's tests were conducted at a snail's pace (literally) and at a perfect angle of approach—neither of which ever occur in the real world.

JA11323:2-16; JA11328:24-JA11329:10; JA11331:12-13, 19-24. Dr. Hogan further acknowledged that he performed his tests at a slower speed than the speed Applied uses to test its own products. JA11329:11-13; JA11331:15-18. He also confirmed that the control samples used in his experiments—the trocars having guard members of uniform thickness—were specially created by Applied for testing in this case. JA11315:4-14; JA11321:10-24; JA11331:6-11. Dr. Hogan also admitted that before Applied retained him for this case, he had no expertise in trocars nor had he ever previously seen or tested a trocar. JA11310:11-18.

So while Applied asserts that it presented "unrebutted test results" (Applied Br. at 28), there was substantial evidence that Dr. Hogan's testing was flawed. The jury was free to discredit Dr. Hogan's testing and Dr. Miller's reliance on it. Likewise, the jury was free to disregard Dr. Miller's shoehorn arguments. Dr. Miller likened the guard members on a trocar device to that of a shoehorn and said that, if "the bottom of it were made out of paper," he would not be able to get his foot in there.[9] JA11169:9-19; Applied Br. at 24-25, 39. The accused guard members are neither like a shoehorn nor made out of paper.

[9] Dr. Miller's shoehorn analogy is inapposite for other reasons as well. First, most frequent travelers are aware of the trick whereby a flexible leather belt can be used as a makeshift shoehorn. Second, Dr. Miller's analogy fails to account for the fact that flexible guard members distribute spreading forces more evenly. Finally, reduced friction caused by a smooth, yet flexible, guard member also reduces insertion forces.

4. The District Court's Denial of JMOL Should Be Affirmed

The district court's construction of "minimize" from the Smith '377 patent is supported by the plain language of the claim and the specification, and should be affirmed. Likewise, the court's denial of Applied's JMOL of noninfringement of this patent should be affirmed. The jury's verdict was supported by substantial evidence, namely, Mr. Dubrul's testimony based on Applied's documents, his observation of Applied's accused trocars, his testing of the products, and his expertise in the field of trocar design. The jury heard Applied's experts, found them not credible, and this Court should not disturb the jury's finding of infringement.

VII. ARGUMENT FOR TYCO'S CROSS-APPEAL

A. Standard of Review

A district court's claim construction is reviewed *de novo*. *Cybor Corp.*, 147 F.3d at 1362.[10] A district court's decision on summary judgment is, similarly, reviewed *de novo*. *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1362 (Fed. Cir. 1998). Summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In deciding a motion for

[10] *But see Lighting Ballast Control*, Nos. 2012-1014, -1015 (Fed. Cir. Mar. 15, 2013).

summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). "The underlying determination of invalidity, however, must be predicated on facts established by clear and convincing evidence." *Rockwell*, 147 F.3d at 1362.

B. The District Court's Broad Construction of "Means Engageable" Is Erroneous

The parties agree that the disputed limitation in the Green '143 patent is a means-plus-function element under 35 U.S.C. § 112(f) and agree on the recited function. The issue is whether the structure corresponding to the means-plus-function element must be flexible enough to conform to the inner wall of the valve member, consistent with the sole embodiment described in the specification.

1. The '143 Specification Supports Tyco's Construction

The Green '143 patent discloses a single embodiment of "fingers 78," which the parties agree performs the claimed function. According to the specification, fingers 78 "are sufficiently flexible to conform to the shape of the inner wall," "assist in spreading inner wall 30a to expand aperture 34 when an instrument is inserted by distributing the spreading force more evenly," and "are sufficiently thin and flexible such that insertion into inner wall 30a of diaphragm 30 causes them to assume an initial arcuate shape." JA183 at 6:36-61. The patent provides no other structural characteristics of "fingers 78."

This Court's "case law is clear that a means-plus-function claim limitation is limited to the structures disclosed in the specification and equivalents." *Mettler-Toledo, Inc. v. B-Tek Scales, LLC*, 671 F.3d 1291, 1296 (Fed. Cir. 2012). "If a patentee chooses to disclose a single embodiment, then any means-plus-function claim limitation will be limited to the single disclosed structure and equivalents thereof." *Id.* "While corresponding structure need not include all things necessary to enable the claimed invention to work, it must include all structure that actually performs the recited function." *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed. Cir. 2005).

Here, "fingers 78" perform the claimed function ("to facilitate expansion of said aperture of said first valve member") by being flexible enough to conform to the inner wall of the valve member. The specification describes fingers 78 as "sufficiently flexible to conform to the shape of the inner wall while providing some degree of stability to the inner wall." JA183 at 6:43-46. The specification also clearly links the flexibility of the fingers with expansion of the aperture in the way it describes *how* the fingers expand the aperture: fingers 78 "assist in spreading inner wall 30a to expand aperture 34 when an instrument is inserted by *distributing the spreading force more evenly*." *Id.* at 6:46-48 (emphasis added). Thus, the spreading force is distributed evenly because the fingers are sufficiently flexible to conform to the inner wall of the valve member. Or, in the words of the

specification, "the fingers *distribute the force over the inner surface* of the first valve means." JA182 at 4:21-22 (emphasis added).

The district court found the corresponding structure of the "means engageable" limitation is, simply, "fingers 78," and declined to further construe the limitation because the "specification does not clearly link or associate the 'conforming' element to the expansion of the aperture." JA50. But the specification expressly links the structural requirement that the fingers are flexible enough to conform to the inner wall to the function of expanding the aperture. JA183 at 6:43-48. As a result, the requirement that the fingers are able to conform to the inner wall of the valve is a further structural detail that should have been included in the construction.

In *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998), the district court had identified the structure corresponding to the claimed function as "a support surface or plate." This Court held that the district court misidentified the structure, that the corresponding structure was a "skid" plate, and that particular details about the skid plate should have been included in the construction while other parts should not have been included because they were not associated with claimed function. *Id.* The Court concluded that the "corresponding disclosed physical structure is the skid plate, a generally flat hard plate that straddles the leading edge of the cutting blade." *Id.* at

1308-09. Here, the description of the structure of the fingers 78 as sufficiently flexible to conform to the inner wall of the valve is akin to describing the skid plate as a flat hard plate that straddles the leading edge of the cutting blade.

The '143 specification distinguished prior art fingers that operate as levers, which further shows that the district court's construction of the "means engageable" limitation was incomplete. According to the Green '143 patent, "a number of attempts in the prior art" had been made to create an ideal trocar that will maintain a fluid-tight interface between the patient's body and the outside atmosphere. JA181 at 1:66-2:5. One such attempt involved "finger operated levers for controlling an inner valve." *Id.* at 2:24-34. Against this backdrop, the '143 patent discloses the use of flexible fingers that conform to the inner wall of the valve member, rather than operating as rigid levers, to distribute the spreading force more evenly. JA183 at 6:42-61. The district court's claim construction did not account for this structural distinction.

2. The Patent Office Has Confirmed that Flexible Fingers Are Patentably Distinct from Rigid Levers

"[B]ecause. . . interference proceedings are part of the public record and shed light on the meaning of the claims, it is proper to rely on the record of those proceedings in construing the claims." *Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 872 (Fed. Cir. 1998). The interference proceeding here involved a similar means-plus-function limitation and also involved Applied.

The Patent Office previously found that the fingers disclosed in the Green patents are "patentably distinct" from a rigid-lever embodiment. JA28932; JA28935. The proposed count included: "means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area." JA28929. According to the Patent Office (and Applied), despite identical claim language, there was no interference-in-fact because there was no identity of structure: "While Green's thin and flexible 'fingers' may assist in enlarging the orifice by *distributing* the expansive force and spreading it throughout the membrane material when an instrument contacts the fingers, [Applied]'s rigid levers *concentrate* and *focus* the enlarging force in the lateral direction and with a mechanical advantage not obtainable with Green's soft and flexible 'fingers.'" JA28935. Thus, the corresponding structure was different because "Green's soft, thin, and flexible 'fingers' conforming to the conical shape of the valve's inner membrane primarily provides a passive protective coating for the membrane and not a mechanism for actively enlarging the orifice." JA28932.

Not only is the Patent Office's determination highly relevant to the disclosed structure for "fingers 78," but Applied's prior agreement with that construction to avoid an interference should preclude Applied from arguing a different construction in this case. In any event, the Patent Office's determination shows that the district court erred when it did not limit the structure corresponding to the

"means engageable" to fingers that are able to conform to the inner walls of the valve member.

3. The Claim Construction Error Mattered to the Verdict in the First Trial and the Collateral Estoppel Decision in the Second Trial

The district court's erroneous construction led the jury to find claims 12 and 13 of the Green '143 patent invalid for obviousness in the first trial. JA74. It also led the court to hold claims 14 and 31 of the Green '143 patent and claim 4 of the Green '854 patent invalid based on collateral estoppel prior to the second trial. JA120-21 (Order); JA122-30 (Memorandum). The jury in the first trial found the claims invalid even though Applied never presented any evidence that it would have been obvious to one skilled in the art to use flexible fingers like those described and claimed in the '143 patent.

Applied argued to the jury that each element of claims 12 and 13, including "fingers," was separately known in the art. JA10908:2-17. Applied's expert, Dr. Kirsch, viewed "fingers 78" of the Green '143 patent as sharing the same function, or doing the same thing as, "legs 88" in Yoon and "fingers 27" in Bourke. JA10914:1-JA10915:18; JA10916:21-JA10917:15; JA10921:1-11. But there was no evidence Yoon's legs or Bourke's fingers met all the structural requirements of the "means engageable" limitation, i.e., that they were sufficiently flexible so as to conform to the inner wall of the valve member.

Tyco has never disputed that rigid "fingers" were known in the prior art. Indeed, the '143 patent itself distinguishes rigid, finger-operated levers, which were prevalent in the prior art, from the flexible fingers described and claimed in the patent. JA181 at 2:24-34. As the Patent Office confirmed during the interference, the flexible fingers of the '143 patent are "patentably distinct" from rigid, finger-like levers. JA28932; JA28935. Applied agreed with the Patent Office then to prevent its issued patent from entering the interference. Yet the jury was unable to consider this distinction because of the district court's claim construction.

Because the district court erred in construing the "means engageable" limitation, the jury's verdict of invalidity of claims 12 and 13 of the Green '143 should be vacated. The court's additional holding that claims 14 and 31 of the Green '143 patent and claim 4 of the Green '854 patent are invalid based on collateral estoppel should also be reversed.

C. The District Court Failed to Construe the Dual-Rigidity Limitations of the Smith Patents in the Second Trial

The district court committed a similar error concerning the Smith patents during the second trial. This time the disputed limitations were not drafted in means-plus-function form. The disputed limitations are: (a) "a first substantially rigid portion," and (b) "a second portion having less rigidity than the first portion." Although the court had adopted a "plain meaning" construction (over Tyco's

objection), Applied's counsel continued to argue to the jury that "rigidity," as used in the Smith patents, actually meant "thickness."

1. *O2 Micro* Requires the District Court to Resolve Disputes Concerning the Scope of Claim Limitations

In *O2 Micro Int'l, Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008), this Court held that, "[w]hen the parties raise an actual dispute regarding the proper scope of [the] claims, the court, not the jury, must resolve that dispute." The Court in *O2 Micro* distinguished situations where the parties dispute the *meaning* of a claim term (where a "plain meaning" construction is appropriate) and situations where the parties dispute the *scope* of a claim term (where a plain meaning construction may not resolve that dispute). *Id.* at 1360-61. The facts of *O2 Micro* fell into the latter situation.

In *O2 Micro*, the parties did not dispute that "only if" has an ordinary meaning. Instead, the parties disputed what the patent meant when it used the words "only if" and, particularly, which circumstances satisfied the requirement specified by the claim. *Id.* Because the district court did not resolve the parties dispute, they instead presented their arguments over claim scope to the jury, include expert and inventor testimony. *Id.* at 1358, 1362. On appeal, this Court held that the parties' arguments on claim scope and the legal significance of the limitation were improperly submitted to the jury. *Id.* The Court vacated the jury's

verdict and remanded the case for the district court to resolve the disputed claim scope. *Id.* at 1362-63.

2. Applied's Claim-Construction Arguments Placed the Scope of the Disputed Limitation Before the Jury

The facts of this case are on all fours with *O2 Micro* and the result should be the same. In its opening statement, Applied postured the case to the jury as "a real dispute as to what [Tyco] think[s] the Smith patent is all about." JA23271:12-19. Although the parties here went into the jury trial with a "plain meaning" construction, Applied's arguments to the jury about the scope of the rigidity limitations placed the dispute over claim scope squarely before the jury. Applied presented testimony from a co-inventor supporting its view that the claimed rigidity limitation was limited to variations in thickness. JA24881:1-JA24888:13. Applied's expert further testified that (a) according to the inventor's testimony "the way to vary rigidity was varying the thickness," and (b) the claims do not encompass "varying rigidity by folding." JA25048:2-JA25049:14.

The district court, after repeated objections from Tyco's counsel, agreed that Applied's claim-construction arguments had crossed the line. The court denied Tyco's motion for mistrial and decided that it must construe the claims. JA25060:19-25. Despite that the jury had already heard impermissible claim-construction arguments, the court nonetheless refused to construe the claims to avoid pushing the trial into a second week. JA25061:3-JA25062:22. The jury was

left to reconcile a plain-meaning construction for the disputed rigidity limitations with the competing arguments over the scope of that claim. JA25561 (jury instruction that terms not construed are to be given plain meaning); JA25594 (no construction provided for disputed claim term).

Here, as in *O2 Micro*, "the parties' arguments regarding the meaning and legal significance of the [disputed] limitation were improperly submitted to the jury." 521 F.3d at 1362. In his closing argument, Applied's counsel continued to present improper claim-construction arguments to the jury: "Any doubt what the invention was in Mr. Smith's mind? Changing the thickness . . . . Now we know what the invention is . . . . It really requires dual thickness." JA25711:8-JA25714:25.

3. Tyco Was Harmed by the Claim Construction Error

The district court's refusal to resolve the dispute over the scope of the rigidity limitation affected the jury's verdict on infringement and validity. Through its arguments, Applied was able to turn the dual-rigidity limitation into whatever it needed for infringement and invalidity. Applied's infringement defense was based primarily on the testimony that its accused trocars cannot satisfy the rigidity limitations because they have a uniform thickness. *See, e.g.*, JA25080:3-13. Similarly, Applied's invalidity defense was also based on Applied's characterization of the claim as requiring dual-thickness guard members,

rather than guard members having at least two portions of differing rigidity, as claimed. *See, e.g.*, JA25102:10-JA25103:24.

The lack of guidance from the court on the scope of this term led to overall jury confusion. *See Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1337 (Fed. Cir. 2009) ("We have held that it is improper to argue claim construction to the jury because the 'risk of confusing the jury is high when experts opine on claim construction.'" (quoting *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172-73 (Fed. Cir. 2005))).

VIII. CONCLUSION

The district court's construction of "minimize" in the Smith '377 patent is supported by the plain language of the claim, the specification, and extrinsic evidence. It should be affirmed.

The district court's denial of Applied's motion for JMOL of noninfringement of the Smith '377 patent should be affirmed. The jury's verdict was supported by substantial evidence. Mr. Dubrul, Tyco's technical expert, testified based on Applied's documents, his observation of Applied's accused products, his tests on those products, and his expertise in the field of trocar design. The jury was free to disregard Applied's testing evidence, which had been discredited.

The district court's broad construction of "means engageable" in the Green patents was improper because it was not limited to the structure described in the specification, i.e., flexible fingers that conform to the inner wall of the valve member. The Green specification clearly links this structure to the claimed function of spreading the inner wall to facilitate expansion of the aperture. The district court's construction also ignores the distinction recognized by the Patent Office that flexible fingers (described in the Green patents) are patentably distinct from rigid levers. The court's construction allowed the jury to find the Green patents invalid based on prior art that only disclosed rigid, lever-like fingers. This Court should construe "means engageable" to mean a flexible strip of plastic that can conform to the inner wall of the valve member, vacate the jury's finding of invalidity in the March 2010 trial, reverse the district court's grant of summary judgment based on collateral estoppel, and remand.

Finally, the district court should have construed "substantially rigid" in view of Applied's improper attempts to redefine the claim. This Court should clarify the proper construction of the rigidity limitations to mean "a region that is sufficiently flexible to assist expansion of the aperture of the seal member" and "another region that has less rigidity, i.e., more flexibility, then the first to enhance passage of the elongated object through the valve body." The Court should also vacate the jury's

finding of noninfringement and invalidity in the 2011 trial, and remand the case for a new trial.

Date: January 30, 2014

Respectfully submitted,

/s/ J. Michael Jakes

J. Michael Jakes
Kathleen A. Daley
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Jacob A. Schroeder
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
3300 Hillview Avenue
Palo Alto, CA 94304-1203
(650) 849-6600

Attorneys for Plaintiffs-Cross Appellants
Tyco Healthcare Group LP and
United States Surgical Corporation

CERTIFICATE OF SERVICE

I certify that on January 30, 2014, this BRIEF OF PLAINTIFFS-CROSS APPELLANTS TYCO HEALTHCARE GROUP LP and UNITED STATES SURGICAL CORPORATION was filed electronically using the CM/ECF system and served via the CM/ECF system on counsel for Defendant-Appellant as follows:

Joseph R. Re
KNOBBE MARTENS OLSON & BEAR, LLP
2040 Main Street, Fourteenth Floor
Irvine, CA 92614

/s/ J. Michael Jakes

CERTIFICATE OF COMPLIANCE

I certify that this BRIEF OF PLAINTIFFS-CROSS APPELLANTS TYCO HEALTHCARE GROUP LP AND UNITED STATES SURGICAL CORPORATION contains 16,352 words as measured by the word processing software used to prepare this brief.

/s/ J. Michael Jakes

ADDENDUM

TABLE TO ADDENDUM

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

TYCO HEALTHCARE GROUP LP AND UNITED STATES SURGICAL CORP.,	§	
Plaintiffs,	§	Civil Action No. 9:09-CV-176
v.	§	JUDGE KEITH F. GIBLIN
APPLIED MEDICAL RESOURCES CORP.,	§	
Defendant.	§	

FINAL JUDGMENT

Plaintiff Tyco Healthcare Group LP originally filed suit against Defendant Applied Medical Resources Corporation in 2006 claiming infringement of certain United States patents relating to valve assemblies.[1] *See* 9:06-cv-151. After a dispute over ownership in 2009, United States Surgical Corporation was added as a plaintiff and the instant new case was filed. In the new case, Tyco and USSC (collectively "Tyco") accused the products already at issue in the -151 case, and added allegations regarding products Applied had begun selling that were supposedly modified versions of the previously accused products.

The first trial was held in March 2010 regarding the original accused products, with trial regarding the new accused products held in September 2011. The jury in the March 2010 case found that: (1) Applied's trocar products having septum shields with dual-thickness guard members infringed Claim 6 of United States Patent No. 5,895,377; (2) Claims 12 and 13 of United States Patent No. 5,304,143 were invalid as obvious; and (3) awarded Tyco damages in the amount of

[1]United States Patent Nos. 5,304,143, 5,685,854, 5,603,702, 5,895,377, and 5,542,931. The '931 patent was never submitted to the jury in either case.

$4,810,389. Doc. # 105. Post-trial, the court denied each parties' motions for judgment as a matter of law; upheld the jury verdict; denied Tyco's request for a permanent injunction; and granted Tyco's motion for pre-judgment interest at the prime rate, compounded quarterly, from February 3, 2004 through the date judgment is entered. Docs. # 138, 313.

Prior to the September 2011 trial, the court granted Applied's motion for summary judgment that Claims 14 and 31 of the '143 patent and Claim 4 of United States Patent No. 5,685,854 were invalid on collateral estoppel grounds. Doc. # 306. A written order explaining the court's reasons why is entered contemporaneously with this Order and Final Judgement.

The jury in the September 2011 trial found that: (1) Applied did not infringe Claims 1 and 2 of the '377 patent or Claims 1 and 5 of United States Patent No. 5,603,702; and (2) Claims 1 and 2 of the '377 patent, as well as Claims 1 and 5 of the '702 patent, were invalid as anticipated and obvious. Doc. # 352.

To the extent that any motions remain pending after the court's rulings at or after these trials, including any motions for judgment as a matter of law, the court now DENIES these motions and enters judgment in accordance with the above:

IT IS THEREFORE ORDERED that:

1. In accordance with the March 19, 2010 jury verdict and the court's subsequent Orders, Plaintiffs Tyco Healthcare Group LP and United States Surgical Corporation are awarded damages in the amount of Four Million Eight Hundred Ten Thousand Three Hundred Eighty-Nine Dollars and Zero Cents ($4,810,389.00), along with pre-judgment interest at the prime rate running from February 3, 2004 through the date of this judgment[2] and post-judgment interest at the rate of 0.13%.

[2]The court recognizes that Applied has a different date in mind for the end date on pre-judgment interest (namely May 18, 2010, which was the day after the court ruled on pending post-trial motions). Given the unique procedural posture of this case, the court concludes that the pre-judgment interest rate should run through the date of judgment.

2. Also in accordance with the March 19, 2010 jury verdict, Claims 12 and 13 of United States Patent No. 5,304,143 are INVALID as obvious.

3. In accordance with the court's September 20, 2011 Order granting Applied's motion for summary judgment, Claims 14 and 31 of the '143 patent and Claim 4 of United States Patent No. 5,685,854 are INVALID on collateral estoppel grounds.

4. In accordance with the October 7, 2011 jury verdict, Plaintiffs shall TAKE NOTHING of and from their claims against Applied with respect to Claims 1 and 2 of the '377 patent or Claims 1 and 5 of United States Patent No. 5,603,702.

5. Also in accordance with thed October 7, 2011 jury verdict, Claims 1 and 2 of the '377 patent or Claims 1 and 5 of United States Patent No. 5,603,702 are INVALID as anticipated and obvious.

6. Applied's counterclaim that the claims of United States Patent No.5,685,854 are invalid for obvious-type double patenting is DISMISSED AS MOOT.

7. Costs are awarded to the prevailing party. The court is not ruling at this time as to which side should be awarded costs for which phase of the trial, but notes that Plaintiffs generally prevailed as to the March 2010 trial and Applied as to the September 2011 trial. The parties should keep this in mind when filing any requests for costs.

8. All pending motions are DENIED. Any and all claims and counterclaims not specifically addressed in this judgment are DISMISSED WITH PREJUDICE. This excludes any motions the parties are entitled to file under the Federal Rules of Civil Procedure or the Local Rules for the Eastern District of Texas.

SIGNED this the 4th day of September, 2013.

KEITH F. GIBLIN
UNITED STATES MAGISTRATE JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

TYCO HEALTHCARE GROUP LP AND UNITED STATES SURGICAL CORP.,	§	
Plaintiffs,	§	Civil Action No. 9:09-CV-176
v.	§	
	§	JUDGE KEITH F. GIBLIN
APPLIED MEDICAL RESOURCES CORP.,	§	
Defendant.	§	

ORDER CONSTRUING CERTAIN CLAIM TERMS IN THE SMITH PATENTS AND DENYING APPLIED'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Tyco Healthcare Group LP originally filed suit against Defendant Applied Medical Resources Corporation in 2006 claiming infringement of certain United States patents relating to valve assemblies. *See* 9:06-cv-151. After a dispute over ownership in 2009, United States Surgical Corporation was added as a plaintiff and the instant new case was filed. In the new case, Tyco and USSC (collectively "Tyco") accused the products already at issue in the -151 case, and added allegations regarding products Applied had begun selling that were supposedly modified versions of the previously accused products. Trial was held in March 2010 regarding the original accused products, with trial regarding the new accused products set for September 2011. Now before the court is Applied's Motion for Summary Judgment of Non-Infringement of United States Patent Nos. 5,603,702 and 5,895,377 (collectively, the "Smith patents"). Doc. # 227.

For the reasons discussed below, the court construes several claim terms in the Smith patents. With these terms properly construed, the court concludes that there are genuine issues of material fact remaining for trial. Applied's motion for summary judgment is denied.

I. CLAIM CONSTRUCTION

The parties submitted yet another claim construction dispute to the court for resolution in connection with the Smith patents. Namely, they agree that two claim terms—"a first substantially rigid portion" and "a second portion having less rigidity than the first portion"—need to be construed, but dispute whether a third claim term—"wherein the at least one guard includes a plurality of guard members coaxially arranged about the central longitudinal axis"—needs construction. After consideration of the patents, prosecution history, and the parties' briefing and arguments, the court construes these terms as follows.

A. "A first substantially rigid portion." Found in claim 1 of both the '702 and '377 patents.

B. "A second portion having less rigidity than the first portion." Found in claim 1 of both the '702 and '377 patents

With respect to "a first substantially rigid portion," Tyco suggests that this term be construed as "a region that is sufficiently rigid to assist expansion of the aperture of the seal member" while Applied proposes "a proximal portion (i.e., the first portion the inserted instrument would encounter) that is substantially devoid of flexibility." With respect to "a second portion having less rigidity than the first portion," Tyco suggests that this term be construed as "another region that has less rigidity, i.e. more flexibility, than the first to enhance passage of the elongated object through the valve body," while Applied proposes "a distal portion that is less rigid as compared to the proximal portion of the guard member." In context, the claim language reads as follows:

> Valve assembly for sealed reception of an elongated object, which comprises . . .
>
> a plurality of elongated guard members . . . each of the guard members including at least a **first substantially rigid portion** and **a second portion having less rigidity than the first portion** . . . .

'702 patent, claim 1.

Taking Tyco's arguments first, the Smith patent specifications state, under the heading "Summary," the following:

> The guard member includes at least a first substantially rigid portion adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member and a second portion having less rigidity than the first portion of the guard member to enhance passage of the elongated object through the valve body.

See, e.g., '702 patent, col. 3:23-29. This is not a preferred embodiment. As the specification clearly states, the first substantially rigid portion facilitates expansion of the aperture of the seal member, and the second less rigid portion enhances passage of the elongated object through the valve body.

At the same time, including the language quoted above in the court's construction of "first substantially rigid portion" would be redundant of other language already in the claims. *See, e.g.*, '702 patent, claim 1 (each guard member is "adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member")' '377 patent, claim 1 (the guard member is "adapted to be displaced relative to the longitudinal axis . . .to thereby facilitate expansion of the aperture of the seal member"). Tyco's proposal would render other parts of these claims redundant, which is generally disfavored. *Merck & Co., Inc. v. Teva Pharmas. USA, Inc*., 395 F.3d 1364, 1372 (Fed. Cir. 2005).

This redundancy is not true for "a second portion having less rigidity than the first portion," but while Tyco is correct that the specification indicates this is what the second portion does, there

is no reason given why this must therefore be part of the construction. Every possible adjective or description of a claim term does not need to be in the construction, unless it is required to resolve a dispute over claim scope. Here, Tyco offers no reason why the function of the second portion needs to be included in the claim term to resolve a question of claim scope. Further, this is a structural claim term, and as a general rule, "[w]here a claim uses clear structural language, it is generally improper to interpret it as having functional requirements." *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002).

Turning to Applied's arguments, the court first rejects Applied's argument that the "first" portion must be the "proximal" portion of the guard member and the "second" portion must be the "distal" portion of the guard member. Applied is correct that the Smith patent specifications consistently equate first with proximal and second with distal, *see* '377 patent col. 7:17-20, but, unlike the cases Applied cites, the specification does not lead the reader to conclude that this is the only configuration that the claims cover, rather than simply a preferred embodiment of the invention. *See, e.g., Honeywell Int'l, Inc. v. ITT Indus., Inc*., 452 F.3d 1312, 1318 (Fed. Cir. 2006). In fact, a number of claims in the '702 (claims 6-17) and '377 (claims 6 and 7) patents utilize "proximal" and "distal," rather than "first" and "second," indicating that the terms are not interchangeable.

And while Applied is also correct that there is some indication in the prosecution history that the applicants may have distinguished prior art by describing the first and second portions as proximal and distal, the applicants' remarks are far from the "clear disavowal or contrary definition" required to limit "first" and "second" to "proximal" and "distal." *See, e.g., August Tech. Corp. v. Camtek, Ltd.*, –F.3d–, 2011 WL 3659357 at *6 (Fed. Cir. Aug. 22, 2011).

Based on the above, the court will not construe "a first substantially rigid portion" any further. Tyco's suggestion, while perhaps correct based on the specification, uses unnecessary and redundant functional language to define a structural term. Applied's correlation of "first" with "proximal" is insufficiently supported by the specification and prosecution history. And as Applied concedes, the Smith patent uses "substantially rigid" in the "common ordinary way." Doc. # 247 at 7. Applied's proposal to substitute "devoid of flexibility" for "rigid" makes the term no clearer for the jury than using "rigid" would.[1]

As to "a second portion having less rigidity than the first portion," the court rejects Tyco's proposal for the same reasons discussed above. Applied's substitution of "distal" for "second" is again rejected. This term needs no further construction.

C. "Wherein the at least one guard member includes a plurality of guard members coaxially arranged about the central longitudinal axis." Found in claim 2 of the '377 patent

The parties agree that "plurality" means "at least two." Tyco asserts that the term needs no further construction, while Applied seeks to clarify the language and construe the term as "The valve assembly has at least two guard members coaxially arranged about the central longitudinal axis."

[1]The court is well-aware of its obligation under O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd., 521 F.3d 136162 (Fed. Cir. 2008) to construe claim terms if the dispute goes to scope. However, the parties' briefing leads the court to conclude that the parties' squabble is not about claim scope at all, but instead about rewording the terms at issue to include or exclude the accused products. "A claim is construed in the light of the claim language . . . not in light of the accused device." *Cohesive Techs., Inc. v. Waters Corp*., 543 F.3d 1351, 1367 (Fed. Cir. 2008) (internal quotation omitted; alteration in original). As the parties have not presented a reason why the terms need to be further construed, the court will not do so.

Claim 2 states in its entirety:

> The valve assembly according to claim 1 wherein the at least one guard member [which is contained in limitation (c) in claim 1] includes a plurality of guard members coaxially arranged around the central longitudinal axis.

The only real objection Tyco voices is that Applied's proposed construction may violate 35 U.S.C. § 112 by creating a dependent claim that fails to further narrow a limitation of the claim from which it depends.

The court agrees that the claim term is confusing as written, but is cognizant of Tyco's potential Section 112 problem. To that end, the court will construe claim 2 in its entirety to read as follows: **"The valve assembly according to claim 1, wherein the "at least one guard member" limitation in Claim 1(c) includes at least two guard members coaxially arranged about the central longitudinal axis."** The jury will be so instructed.

II. APPLIED'S MOTION FOR SUMMARY JUDGMENT

A. Summary judgment standard

A party may move for summary judgment on all or part of a claim. Fed. R. Civ. P. 56(a). A summary judgment motion should be granted if "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The party moving for summary judgment under Fed. R. Civ. P. 56 has the burden of demonstrating that no material fact issue exists. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S. Ct. 2505, 2514 (1986). If the moving party meets this burden, then the non-moving party, must bring forth affirmative evidence in order to defeat the summary judgment motion. *Id.* at 257, 106 S. Ct. at 2514. The non-moving party, "must do more than simply show that there is some

metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356 (1986).

Only a genuine dispute over a material fact—a fact which might affect the outcome of the suit under the governing substantive law—will preclude summary judgment. *Anderson,* 477 U.S. at 248, 106 S. Ct. at 2510. The dispute in this case is genuine if the evidence is such that a fact-finder, utilizing the proper evidentiary standard, could render a decision in the non-moving party's favor. *See id.* at 255, 106 S. Ct. at 2514 ("[D]etermination of whether a given factual dispute requires submission to a jury must be guided by the substantive evidentiary standards that apply to the case."). Rule 56(c) permits the parties to support their positions by submitting materials that include "depositions, documents, electronically stored information, affidavits or declarations, stipulations[,] . . . admissions, [or] interrogatory answers . . . ." Furthermore, the court must view all facts and the inferences to be drawn from them in the light most favorable to the non-moving party. *Matsushita*, 475 U.S. at 587, 106 S. Ct. at 1356. However, only *reasonable* inferences in favor of the non-moving party can be drawn from the evidence. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 468, 112 S. Ct. 2072, 2083 (1992).

B. Law on infringement

The determination of infringement, whether literal or under the doctrine of equivalents is "a two-step process in which we first determine the correct claim scope, and then compare the properly construed claim to the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1247-48 (Fed. Cir. 1998). Claim construction is an issue of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S. Ct. 1384 (1996). A determination of infringement is normally

a question of fact. *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1300 (Fed. Cir. 2001).

For literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Any deviation from the literal claim language precludes a literal infringement finding. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316,1330 (Fed. Cir. 2001).

The essential inquiry under the doctrine of equivalents is whether the accused product or process contains elements identical to or equivalent to each claimed element of a patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 117 S. Ct. 1040, 1054 (1997). "A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product was insubstantial." *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1364 (Fed. Cir. 2007). One way to do this is by demonstrating "on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." *Id.*

C. Analysis

Tyco asserts claims 1 and 5 of the '702 patent and claims 1 and 2 of the '377 patent. Applied's motion for summary judgment primarily argues that because the pleated skirt shield of the accused trocar products does not have elongated guard members, any substantially rigid portion, or a first and second portion of differing rigidity, it cannot infringe the asserted claims.

Based on a careful and thorough review of the record and the arguments presented, the court is persuaded that there are genuine issues of material fact as to whether the accused product infringes

the asserted claims of the Smith patents. Therefore, the court will deny Applied's motion for summary judgment.

IT IS THEREFORE ORDERED that Defendant Applied Medical Resources Corp.'s Motion for Summary Judgment of Non-Infringement of United States Patent Nos. 5,603,702 and 5,895,377 [Doc. # 227] is DENIED.

SIGNED this the 15th day of September, 2011.

KEITH F. GIBLIN
UNITED STATES MAGISTRATE JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

TYCO HEALTHCARE GROUP LP AND UNITED STATES SURGICAL CORP.,	§	
Plaintiffs,	§	Civil Action No. 9:09-CV-176
v.	§	JUDGE KEITH F. GIBLIN
APPLIED MEDICAL RESOURCES CORP.,	§	
Defendant.	§	

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Tyco Healthcare Group LP originally filed suit against Defendant Applied Medical Resources Corporation in 2006 claiming infringement of certain United States patents relating to valve assemblies.[1] *See* 9:06-cv-151. After a dispute over ownership in 2009, United States Surgical Corporation was added as a plaintiff and the instant new case was filed. In the new case, Tyco and USSC (collectively "Tyco") accused the products already at issue in the -151 case, and added allegations regarding products Applied had begun selling that were supposedly modified versions of the previously accused products.

Trial was held in March 2010 regarding the original accused products, with trial regarding the new accused products set for early 2011. Relevant to this motion, the jury found that claims 12 and 13 of the Green '143 patent were invalid as obvious. Doc. # 105. No other Green patent claims were submitted to the jury, on either the question of infringement or invalidity.

[1]United States Patent Nos. 5,304,143, 5,685,854, 5,603,702, 5,895,377, and 5,542,931. These patents are often referred to by the inventor's name, rather than the patent number, in their motion papers—i.e., the "Green patents" (the '143 and '854 patents), the "Gravener patent" (the '931 patent), and the "Smith patents" (the '702 and '377 patents).

Applied now moves for summary judgment of invalidity of the currently asserted claims of the Green patents—claims 14 and 31 of the '143 patent and claim 4 of the '854 patent—on collateral estoppel grounds, arguing that these three claims are directed to the same basic invention previously found invalid for obviousness.

For the reasons discussed in a forthcoming memorandum, the court will GRANT Applied's Motion for Summary Judgment [Doc. # 166]. The three asserted claims of the Green patents are invalid on collateral estoppel grounds, based on the jury's verdict from the March 2010 trial.

SIGNED this the 20th day of September, 2011.

KEITH F. GIBLIN
UNITED STATES MAGISTRATE JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

TYCO HEALTHCARE GROUP LP AND UNITED STATES SURGICAL CORP.,	§	
Plaintiffs,	§	Civil Action No. 9:09-CV-176
v.	§	JUDGE KEITH F. GIBLIN
APPLIED MEDICAL RESOURCES CORP.,	§	
Defendant.	§	

MEMORANDUM ORDER RE: DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Tyco Healthcare Group LP originally filed suit against Defendant Applied Medical Resources Corporation in 2006 claiming infringement of certain United States patents relating to valve assemblies.[1] *See* 9:06-cv-151. After a dispute over ownership in 2009, United States Surgical Corporation was added as a plaintiff and the instant new case was filed. In the new case, Tyco and USSC (collectively "Tyco") accused the products already at issue in the -151 case, and added allegations regarding products Applied had begun selling that were supposedly modified versions of the previously accused products.

Trial was held in March 2010 regarding the original accused products, with trial regarding the new accused products set for 2011. Relevant to this motion, the jury in the March 2010 case

[1]United States Patent Nos. 5,304,143, 5,685,854, 5,603,702, and 5,895,377. These patents are often referred to by the inventor's name, rather than the patent number, in their motion papers—i.e., the "Green patents" (the '143 and '854 patents), and the "Smith patents" (the '702 and '377 patents).

found that claims 12 and 13 of the Green '143 patent were invalid as obvious. Doc. # 105. No other Green patent claims were submitted to the jury, on either the question of infringement or invalidity.

Applied now moves for summary judgment of invalidity of the currently asserted claims of the Green patents—claims 14 and 31 of the '143 patent and claim 4 of the '854 patent—on collateral estoppel grounds, arguing that these three claims are directed to the same basic invention previously found invalid for obviousness. The court previously entered an order stating that the motion was granted for the reasons to be discussed in a forthcoming memo. Doc. # 306. This memorandum explains the reasons for granting Applied's motion.

I. BACKGROUND

The parties are well-familiar with the background and procedural history of this case[2], and the court will not recite them again here.

Briefly, the Green patents—the '854 patent is a continuation of the '143 patent—both describe a trocar valve assembly adapted for introduction of an elongated object into a patient's body with multiple valves. The question of whether claims 12 and 13 of the '143 patent were invalid as obvious was submitted to the jury. The jury in the March 2010 case was instructed as follows:

> Applied contends that Claims 12 and 13 of the '143 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made in light of one or more of the following prior art references. The following are the prior art references you are able to consider:
>
> (1) United States Patent No. 2,328,948 to Bourke;
>
> (2) United States Patent No. 5,395,342 to Yoon; and

[2]*See, e.g.*, 9:06-cv-151, Order Granting Defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction [Doc. # 255]; 9:09-cv-176, Order Granting Defendant's Motion to Strike [Doc. # 57].

(3) United States Patent No. 4,655,752 to Honkanen.

In addition, you may also consider the additional prior art that was presented which may or may not show the state of the art and common knowledge to those in the field.

Doc. # 100 at 12-13. The jury found both claims obvious, Doc. # 105 at 2, and the court denied Tyco's motion and renewed motion for judgment as a matter of law as to non-obviousness. Doc. # 138 at 1-3.

II. SUMMARY JUDGMENT STANDARD

A party may move for summary judgment on all or part of a claim. Fed. R. Civ. P. 56(a). A summary judgment motion should be granted if "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The party moving for summary judgment under Fed. R. Civ. P. 56 has the burden of demonstrating that no material fact issue exists. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S. Ct. 2505, 2514 (1986). If the moving party meets this burden, then the non-moving party, must bring forth affirmative evidence in order to defeat the summary judgment motion. *Id.* at 257, 106 S. Ct. at 2514. The non-moving party, "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356 (1986).

Only a genuine dispute over a material fact—a fact which might affect the outcome of the suit under the governing substantive law—will preclude summary judgment. *Anderson,* 477 U.S. at 248, 106 S. Ct. at 2510. The dispute in this case is genuine if the evidence is such that a fact-finder, utilizing the proper evidentiary standard, could render a decision in the non-moving party's favor. *See id.* at 255, 106 S. Ct. at 2514 ("[D]etermination of whether a given factual dispute requires

submission to a jury must be guided by the substantive evidentiary standards that apply to the case."). Rule 56(c) permits the parties to support their positions by submitting materials that include "depositions, documents, electronically stored information, affidavits or declarations, stipulations[,] . . . admissions, [or] interrogatory answers . . . ." Furthermore, the court must view all facts and the inferences to be drawn from them in the light most favorable to the non-moving party. *Matsushita*, 475 U.S. at 587, 106 S. Ct. at 1356. However, only *reasonable* inferences in favor of the non-moving party can be drawn from the evidence. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 468, 112 S. Ct. 2072, 2083 (1992).

III. DISCUSSION

Applied argues that summary judgment is appropriate because the previously adjudicated invalidity of claims 12 and 13 of the Green '143 patent precludes Tyco from now contesting the invalidity of claims 14 and 31 of the Green '143 patent and claim 4 of the Green '854 patent. For the reasons discussed below, the court agrees.

A. Applicable law on collateral estoppel

The application of general collateral estoppel will be governed by regional circuit law, while Federal Circuit law will apply to those issues unique to patent law. *See, e.g., Pharmacia & Upjohn Co. v. Mylan Pharmas., Inc*., 170 F.3d 1373, 1381 n.4 (Fed. Cir. 1999).

Collateral estoppel is a question of law, and is premised on the concept that after "an issue of ultimate fact has once been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in any future lawsuit." *Stripling v. Jordan Prod. Co., LLC*, 234

F.3d 863, 868 (5th Cir. 2000) (internal quotation omitted). Collateral estoppel, or issue preclusion[3], is appropriate where: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; and (3) the previous determination was necessary to the decision." *Pace v. Bogalusa City Sch. Bd.*, 403 F.3d 272, 290 (5th Cir. 2005).

> Where obviousness is the basis for the prior invalidity holding, an inquiry into the identity of the validity issue is more properly phrased in terms of the factual inquiries mandated by *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S. Ct. 684, 15 L.Ed.2d 545 (1966) as a prerequisite to such a validity determination. Thus, the inquiry should be whether the nonlitigated claims present new issues as to the art pertinent to the nonlitigated claims; as to the scope and content of that art; as to the differences between the prior art and the nonlitigated claims; and as to the level of ordinary skill in that art. If none of these inquiries raises any new triable issues, then the obviousness determination in the prior proceeding should be equally applicable to the nonlitigated claims.
>
> Perhaps the most convenient way to approach a determination of these issues is . . . to compare the litigated and nonlitigated claims. If they are of identical scope, it readily follows that no new issues bearing on the obviousness determination are presented. On the other hand, such a comparison may reveal some differences of a substantive nature. In that event, it will be necessary to go a step further and determine whether those differences are of a kind that would have been itemized in a *Graham* analysis as a difference between the claim and the prior art, or whether it was known in the prior art and is only a part of the claimed combination as a whole that provides the context in which the obviousness determination is made. If it is only of the latter character, i.e., it is known in the prior art and does not alter the issue as to the differences between the claimed subject matter and the prior art, it is still necessary to assess the importance of the difference to the combination as a whole since it is from that standpoint that the obviousness determination must be made.

Westwood Chem., Inc. v. United States. 525 F.2d 1367, 1375 (Ct. Cl. 1975).[4]

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[3]There are two related doctrines of preclusion: claim preclusion, also referred to as *res judicata*, and issue preclusion, also referred to as collateral estoppel. *Moore v. State Farm Fire & Cas. Co.*, 556 F.3d 264, 273 (5th Cir. 2009). The phrases "collateral estoppel" and "issue preclusion" are used interchangeably in this Order.

[4]The Federal Circuit has adopted as precedent the decisions of the Court of Claims and the Court of Customs and Patent Appeals. *South Corp. v. United States*, 690 F.2d 1368 (Fed. Cir. 1982).

In other words, the court first looks to whether the claims not asserted in the March 2010 trial are of substantially identical scope to the claims asserted in that trial. *See Interconnect Planning Corp. v. Fell*, 774 F.2d 1132, 1136-37 (Fed. Cir. 1985) (citing *Westwood* and framing the question as one of "substantial identity"). "[S]ubstantial identity between claims, a matter of claim interpretation, is a question of law." *Id*. at 1138 n.3. If they are, collateral estoppel applies assuming that the issue was actually litigated in the March 2010 trial and that determination was necessary to the decision.

B. The identical issue was previously adjudicated

1. *Claims 14 and 31of the '143 patent*

The court concludes that the same issue—validity of Claims 14 and 31 of the '143 patent—was previously adjudicated when the jury in the March 2010 trial found that Claims 12 and 13 of the '143 patent were invalid as obvious.

Claim 14 of the '143 patent depends from invalidated Claim 13, and adds only the following limitation to Claim 13: "wherein said proximal end of said first and second valve members is attached to and supported by an annular ring." This is not substantively different from Claims 12 and 13—not only does the '143 specification place no real emphasis on the annular ring and fails to suggest that the ring provides any inventive advantage[5], the prior art used to invalidate Claims 12 and 13 discloses the attachment of the valves to an annular ring (as recited in the additional limitation of Claim 14)[6]. Finally, the court notes that Plaintiffs themselves, in response to an

[5]*See, e.g.*, '143 patent, 5:42-43 and 52-53; 4:53-55; 6:40-42.

[6]*See, e.g.*, Honkanen patent at 3:33-35 and 53-56.

interrogatory that asked them to state the factual basis for their belief that the '143 patent claims were not invalid for obviousness over Yoon and Honkanen, did not mention any limitation of Claim 14.

Claim 31 of the '143 patent depends from Claims 26-30 of the '143 patent. Claim 26 differs from Claim 12 of the '143 patent only insfoar as Claim 26 recites the means to facilitate expansion in fairly broad structural terms while Claim 12 uses a means-plus-function format. This difference in language does not raise a new issue of obviousness; further, the March 2010 jury was expressly instructed that the structure corresponding to the means clause in Claim 12 was the fingers 78 described in the '143 patent specification, which is the same structure encompassed by the means to facilitate expansion clause in Claim 26. Dependent Claims 27-30 add only additional description regarding features of the projecting members, which apply equally to the corresponding structure of the Claim 12 means clause (fingers 78).The legs 88 of Yoon and the fingers 27 of the Bourke reference also satisfies the additional limitations of these claims. *See, e.g.*, Yoon at Figs. 5 and 6, 5:56-62; Bourke at Figs. 2 and 5, 4:12-22.

2. *Claim 4 of the '854 patent*

Claim 4 of the '854 patent likewise raises no new issues of obviousness. As the parties in this case are well-aware, the claims of the '854 patent were copied from an Applied patent to provoke an interference and, as such, use somewhat different terminology than the '143 patent. Claim 4 depends from Claim 1 of the '854 patent, which recites a trocar assembly—as opposed to the valve assembly of the '143 patent—with an elastomeric septum and means for expanding the orifice of the septum. These elements are substantially identical to the elements recited in now-invalidated Claim 12 of the '143 patent .

The septum of the '854 patent, Claim 1 is no different from the first valve member of the '143 patent, Claim 12. The means clause of both claims refers to fingers 78 as the corresponding structure. Claim 1, insofar as it does not include certain limitations of Claim 12 (i.e., the housing and second valve member elements), is actually broader than Claim 12. A broader claim raises no new issues for an invalidity analysis. *See Ormco Corp. v. Align Tech., Inc*., 498 F.3d 1307, 1319 (Fed. Cir. 2007).

Claim 4 of the '854 patent adds the housing element of Claim 12 of the '143 patent to the assembly of Claim 1 of the '854 patent, and recites specific "seating portions" for attaching the septum valve to the housing. These portions are positioned radially outward of the valve orifice, and axially spaced from the orifice. These do not raise any additional differences over the prior art: as noted above, Claim 12 of the '143 patent already included the housing element, and the invalidated claims also recited that the first valve was at least partially within the second valve. In other words, the perimeter of the first valve (the seating portions) had to be spaced axially from the orifice.

C. The issue was actually litigated in the March 2010 trial and determination was necessary to the decision

Neither of these elements can reasonably be disputed. Given the quality of counsel on both sides of the case, the length of time the case was pending, the multiple claim constructions and extended motion practice, and the extensive discovery process, Plaintiffs had a full opportunity to present evidence on the validity Claims 12 and 13 at the March 2010 trial. Plaintiffs, in fact, proceeded at trial from the premise that the validity of '143 patent Claims 12 and 13 were the only issue to be tried with respect to the Green patents. Adjudication of the obviousness issue was clearly necessary to the jury's verdict in the March 2010 trial; it *was* the decision.

IV. CONCLUSION

Because the previously adjudicated invalidity of claims 12 and 13 of the Green '143 patent precludes Tyco from now contesting the invalidity of claims 14 and 31 of the Green '143 patent and claim 4 of the Green '854 patent, summary judgment in Applied's favor is appropriate.

SIGNED this the 4th day of September, 2013.

KEITH F. GIBLIN
UNITED STATES MAGISTRATE JUDGE

US005603702A

United States Patent [19]

Smith et al.

[11] **Patent Number: 5,603,702**

[45] **Date of Patent: Feb. 18, 1997**

[54] **VALVE SYSTEM FOR CANNULA ASSEMBLY**

[75] Inventors: **Robert C. Smith**, Danbury; **Peter W. J. Hinchliffe**, New Haven; **James Correia**, Shelton; **Martin J. Nohilly**, Trumbull; **Kurt Azarbarzin**, Ridgefield; **Richard D. Gresham**, Monroe, all of Conn.

[73] Assignee: **United States Surgical Corporation**, Norwalk, Conn.

[21] Appl. No.: **287,395**

[22] Filed: **Aug. 8, 1994**

[51] **Int. Cl.**[6] **A61M 5/00**; A61M 5/14

[52] **U.S. Cl.** **604/256**; 604/167; 604/264; 251/149.1

[58] **Field of Search** 604/158, 164, 604/167, 256, 264; 251/149.1–149.3; 285/302

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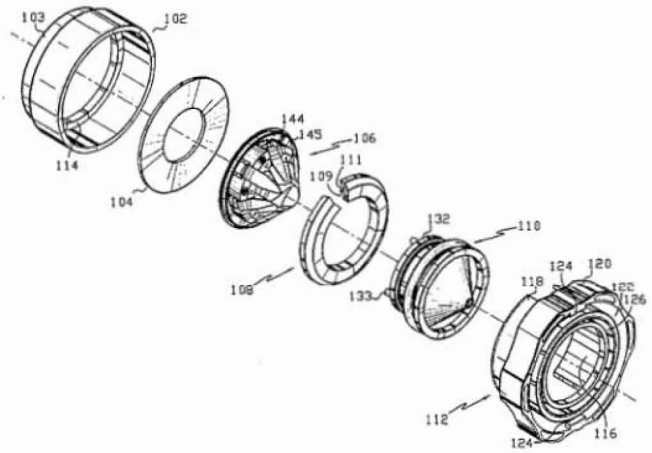
Primary Examiner—Corrine M. McDermott
Assistant Examiner—Ronald K. Stright, Jr.

[57] **ABSTRACT**

Valve assembly for sealed reception of an elongated object includes a valve body having at least one opening configured and dimensioned to permit entry of an elongated object and defining a central longitudinal axis, an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body whereby the aperture is configured and dimensioned such that insertion of the object into the aperture causes the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid flight manner, and at least one elongated guard member disposed within the seal member in supporting contact with the inner surface thereof. The guard member is positioned to engage the elongated object upon at least partial insertion of the elongated object into the valve body. The guard member includes at least a first substantially rigid portion adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member upon entry of the object therein and a second portion having less rigidity than the first portion of the guard member to enhance passage of the elongated object through the valve body.

17 Claims, 13 Drawing Sheets



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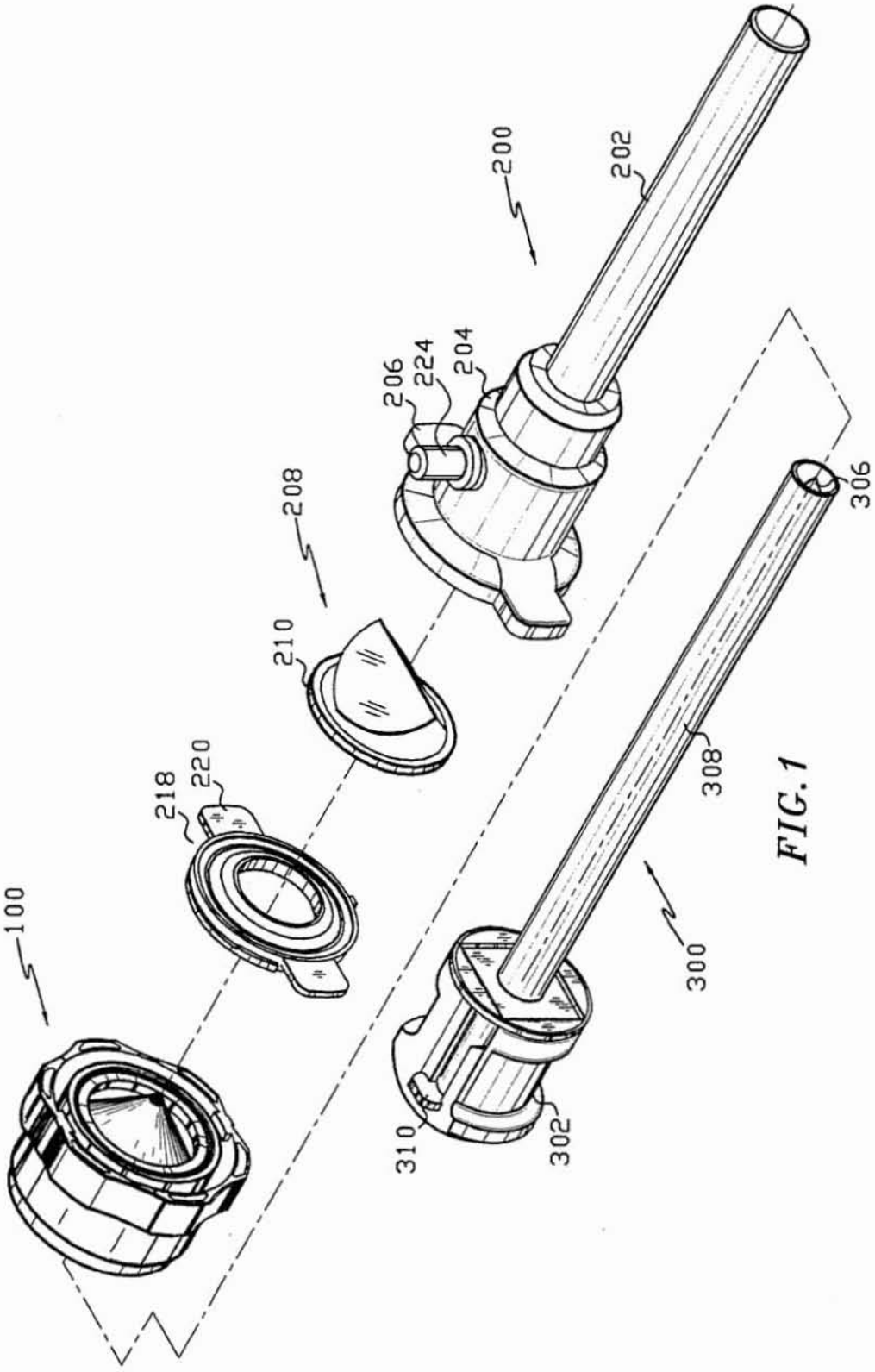

FIG. 1

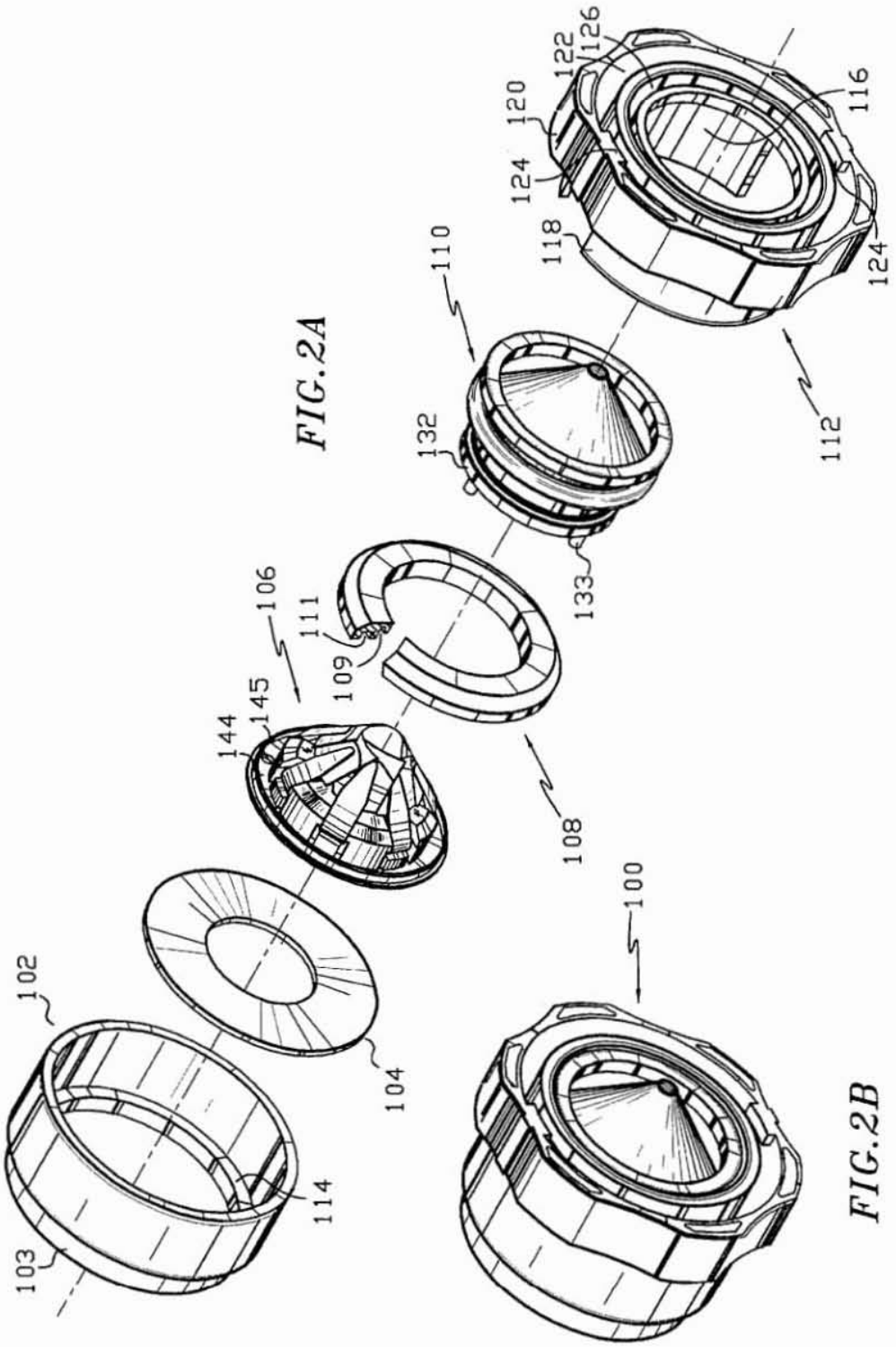
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FIG.2A

FIG.2B

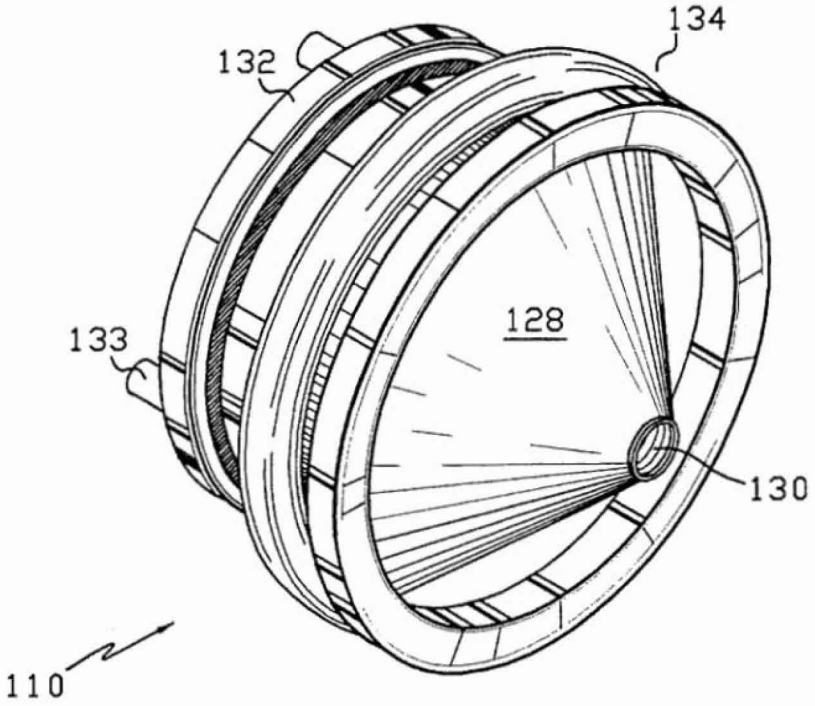

FIG. 3

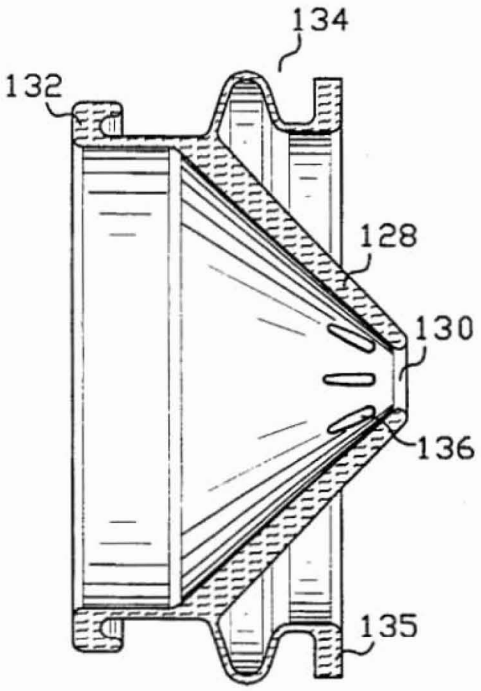

FIG. 4

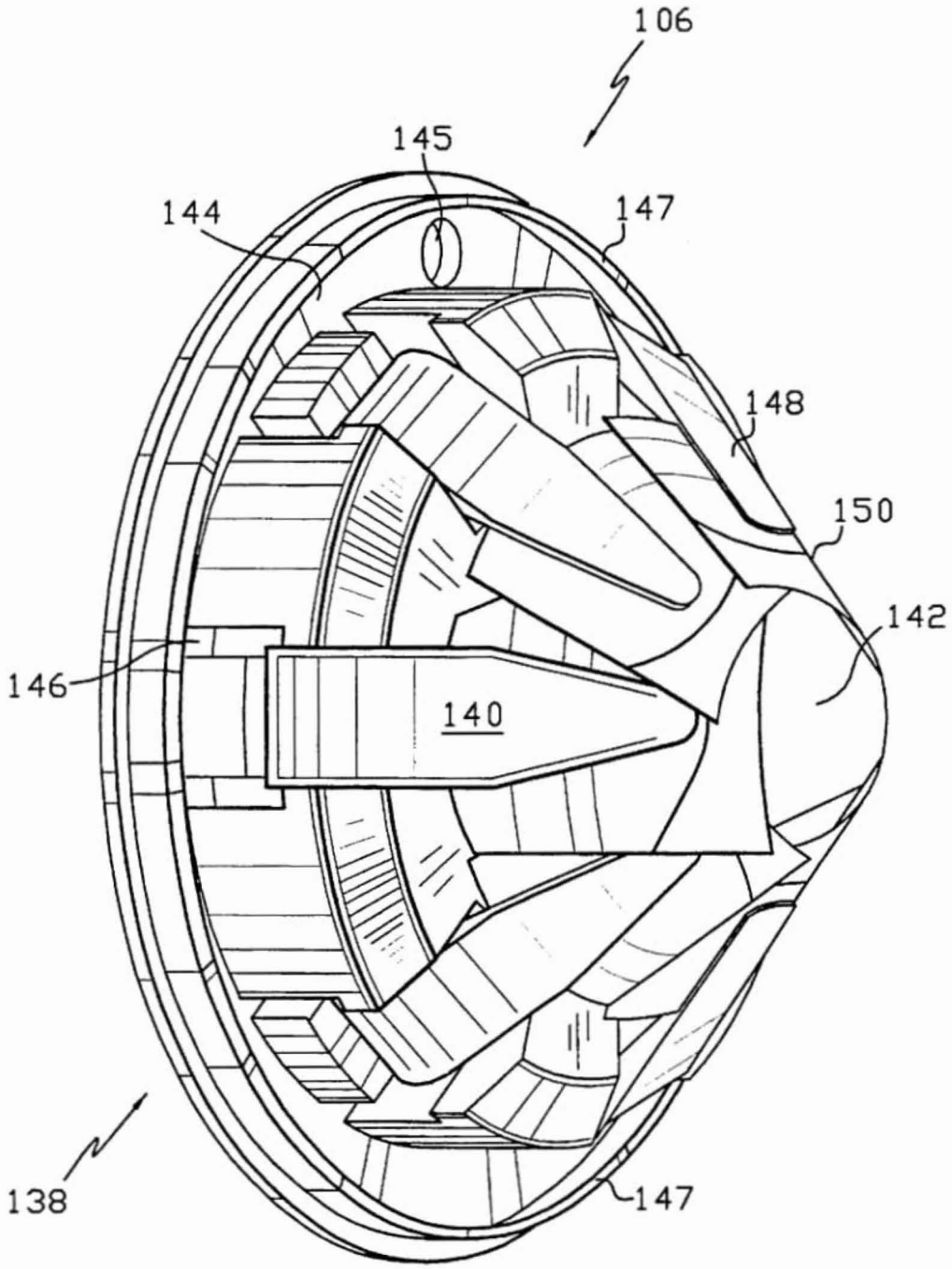

FIG.5

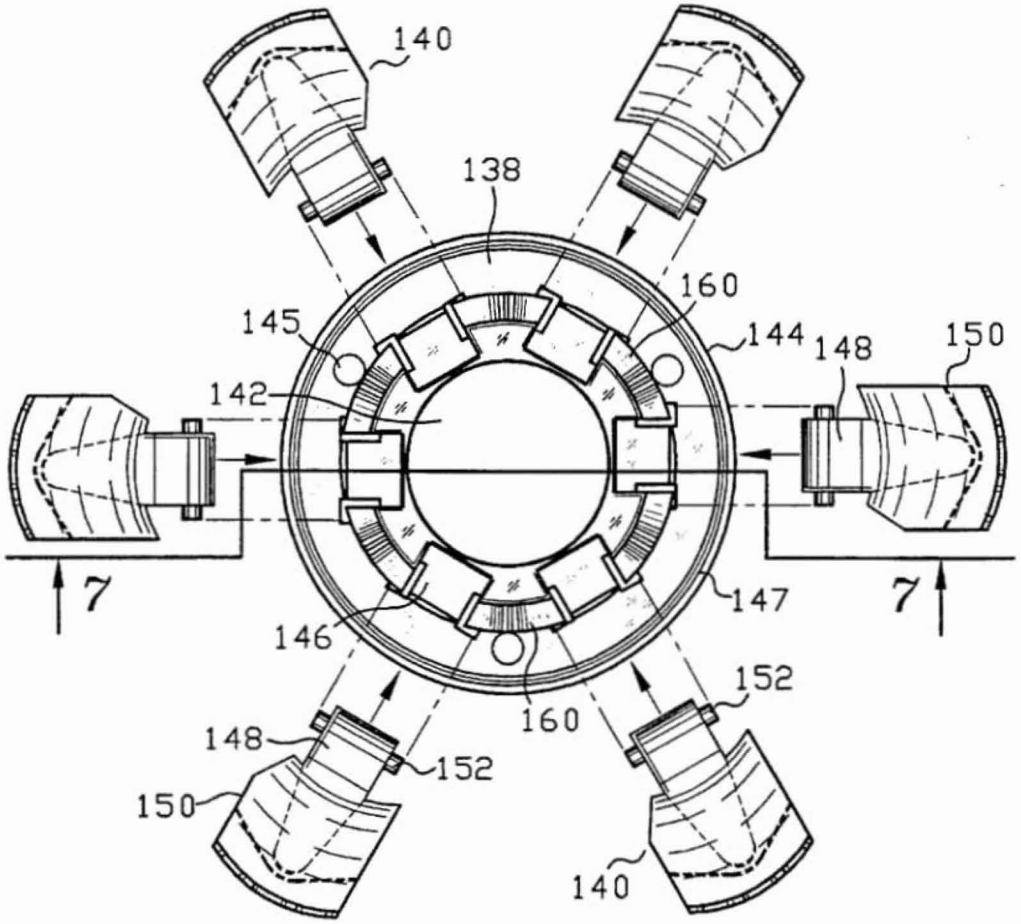
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FIG. 6

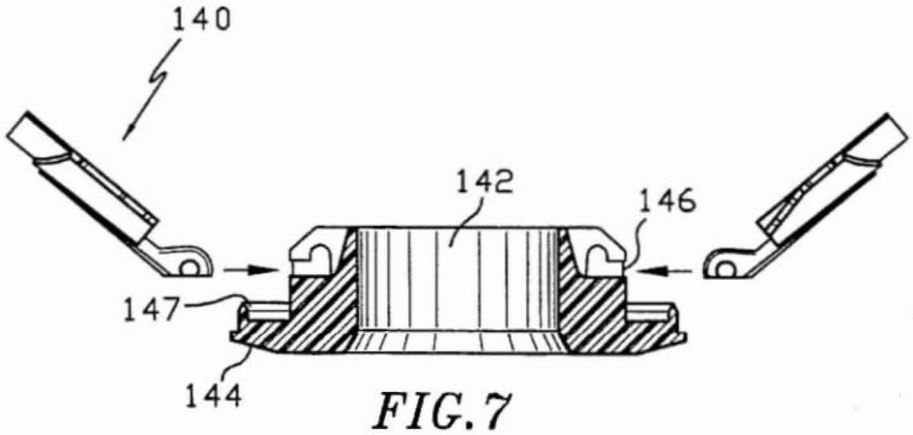
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FIG. 7

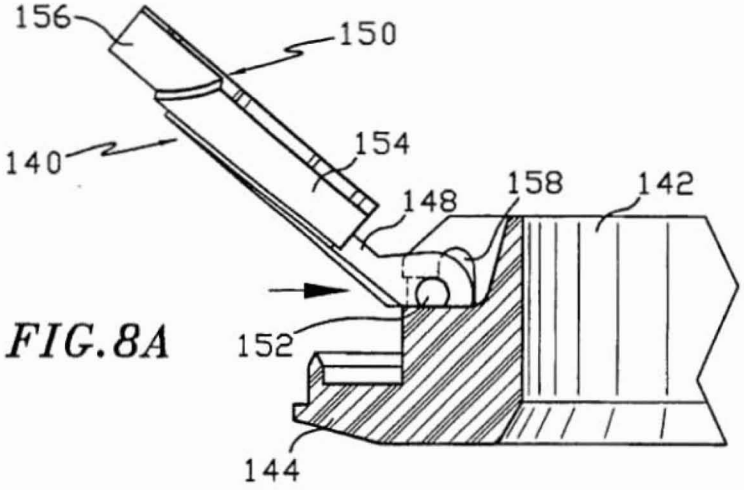


FIG. 8A

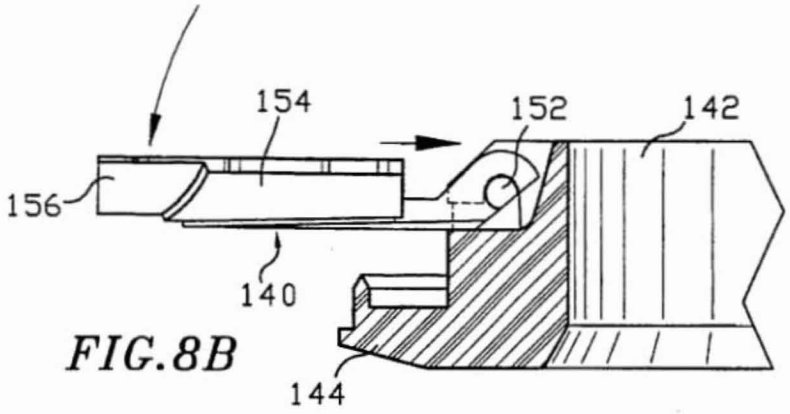


FIG. 8B

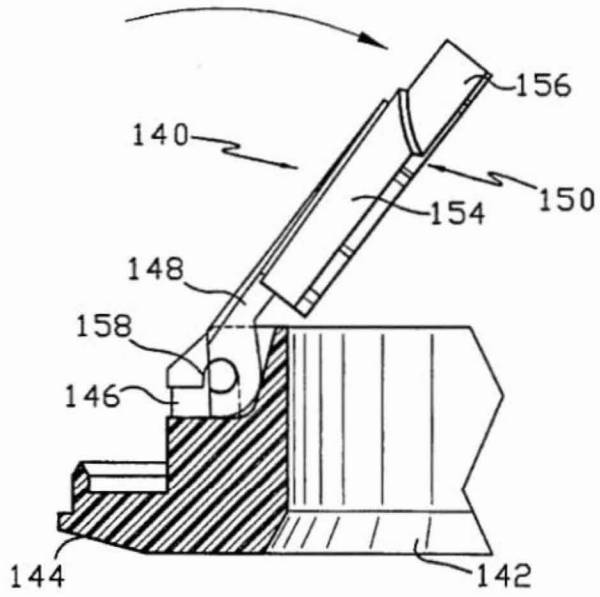


FIG. 8C

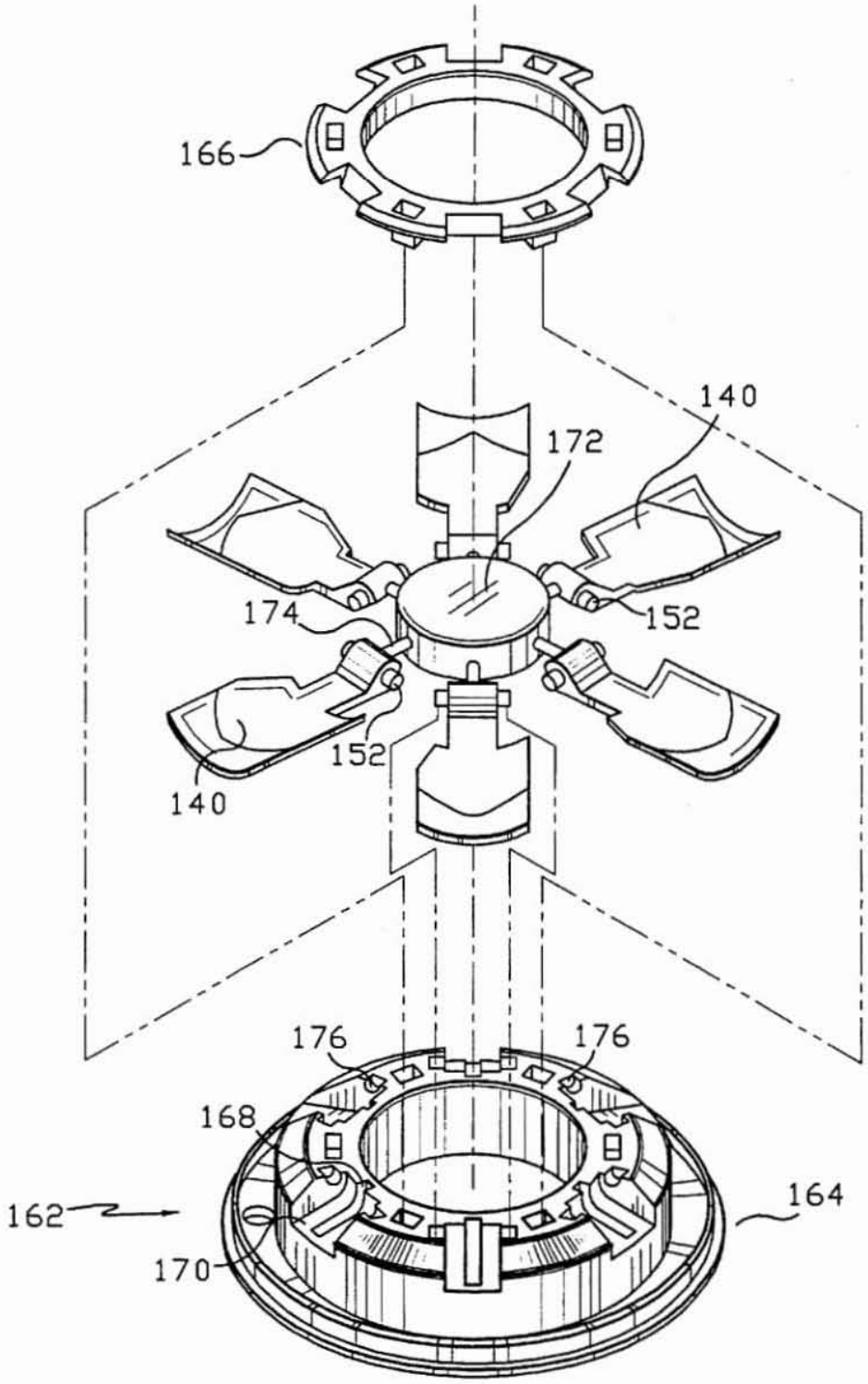


FIG. 9

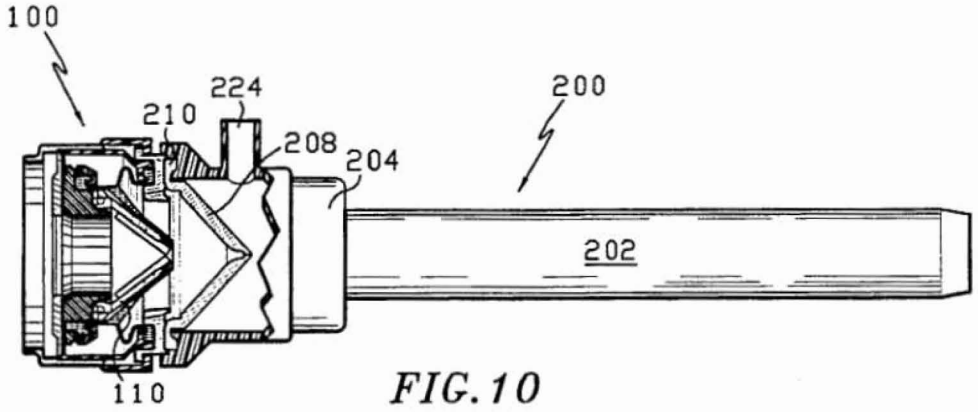

100
224
210
208
204
200
202
110

FIG. 10

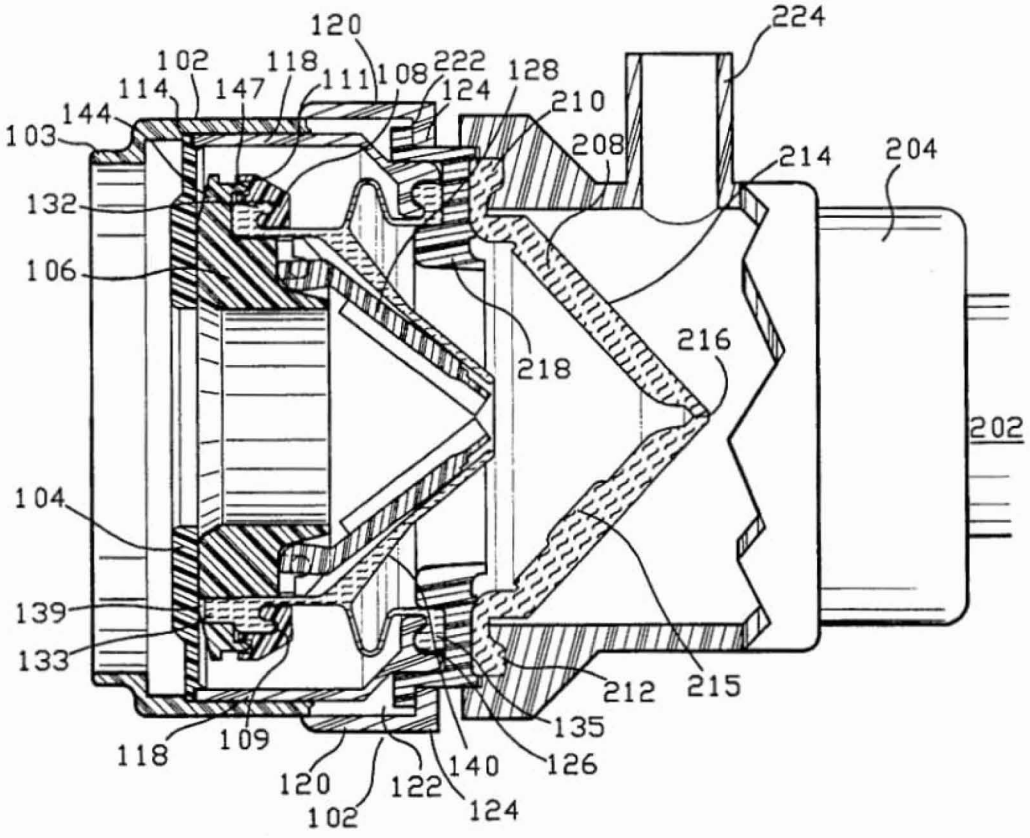

120
102
118
111
108
222
128
224
114
147
124
210
144
103
208
214
204
132
106
218
216
202
104
139
133
212
215
135
118
109
140
126
120
122
124
102

FIG. 11

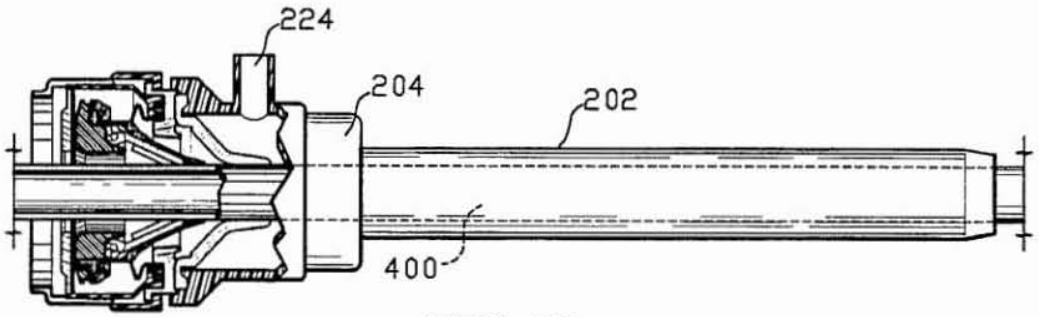


FIG. 12

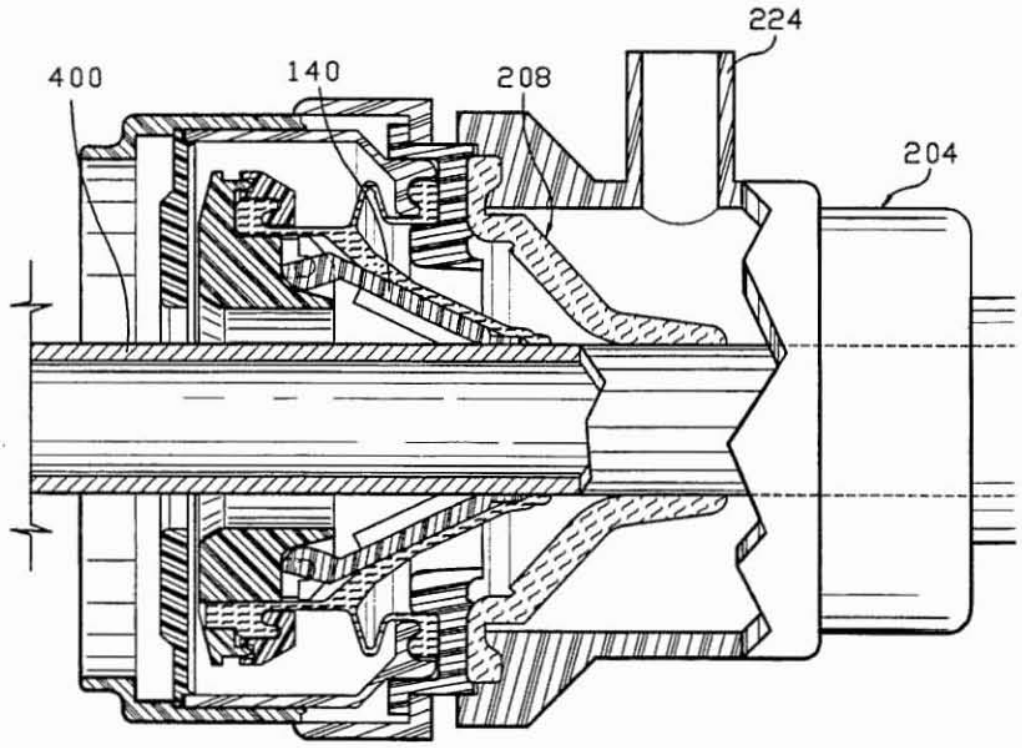


FIG. 13

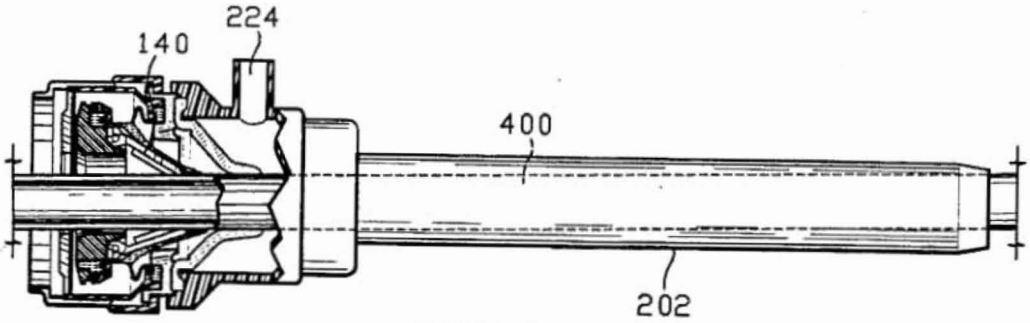


FIG. 14

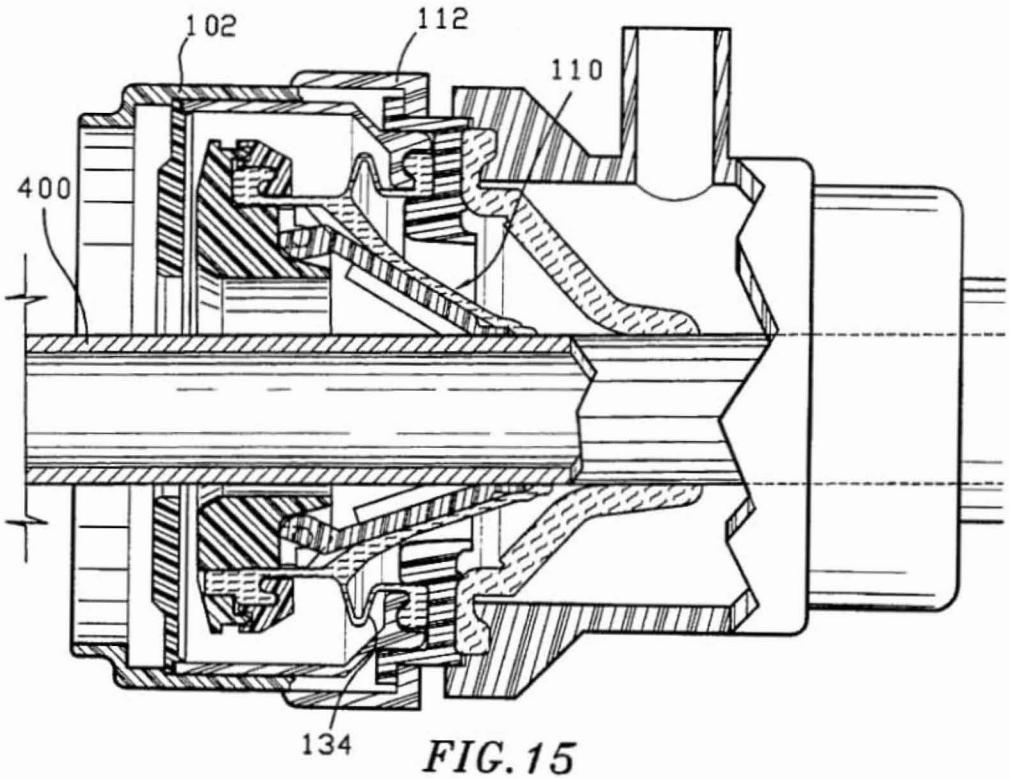


FIG. 15

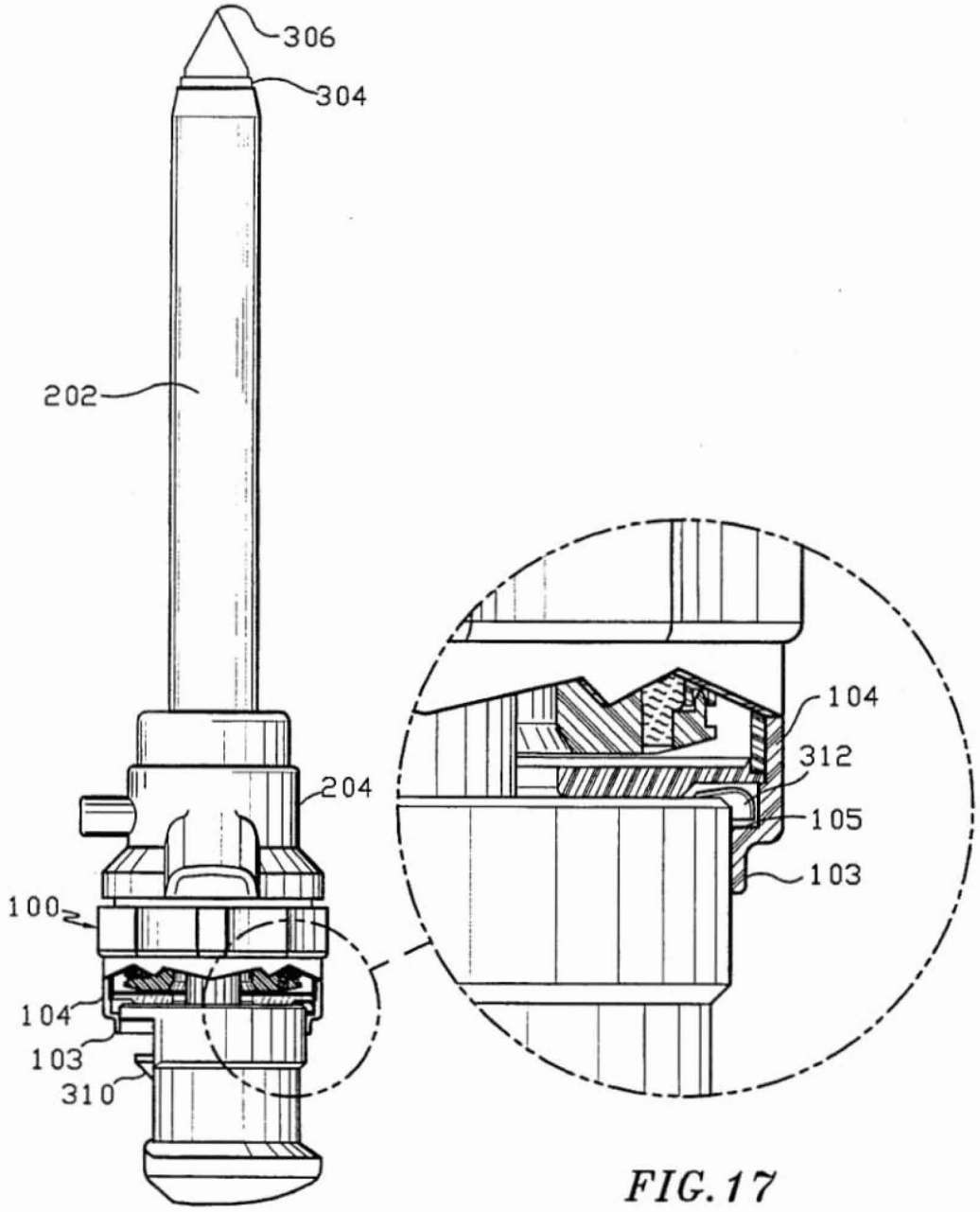
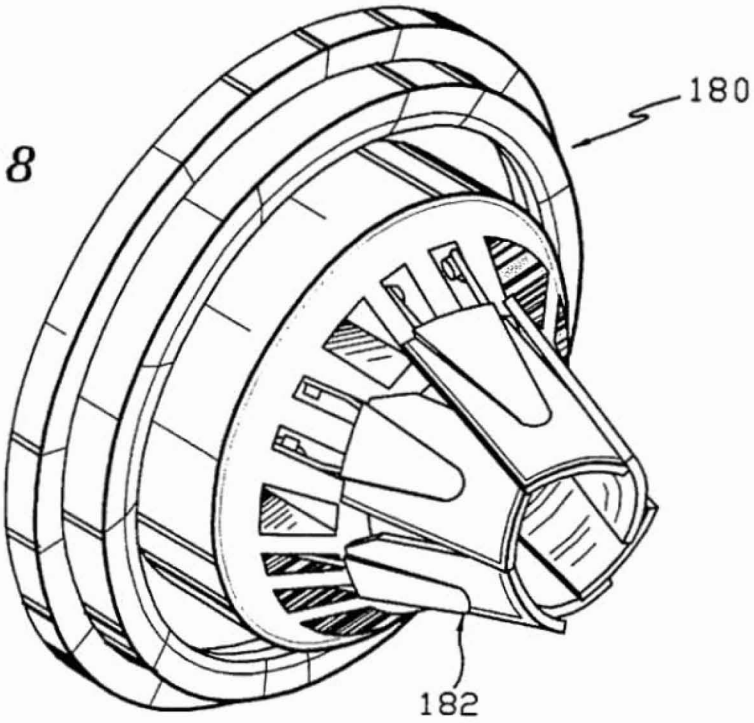


FIG. 16

FIG. 17

FIG. 18



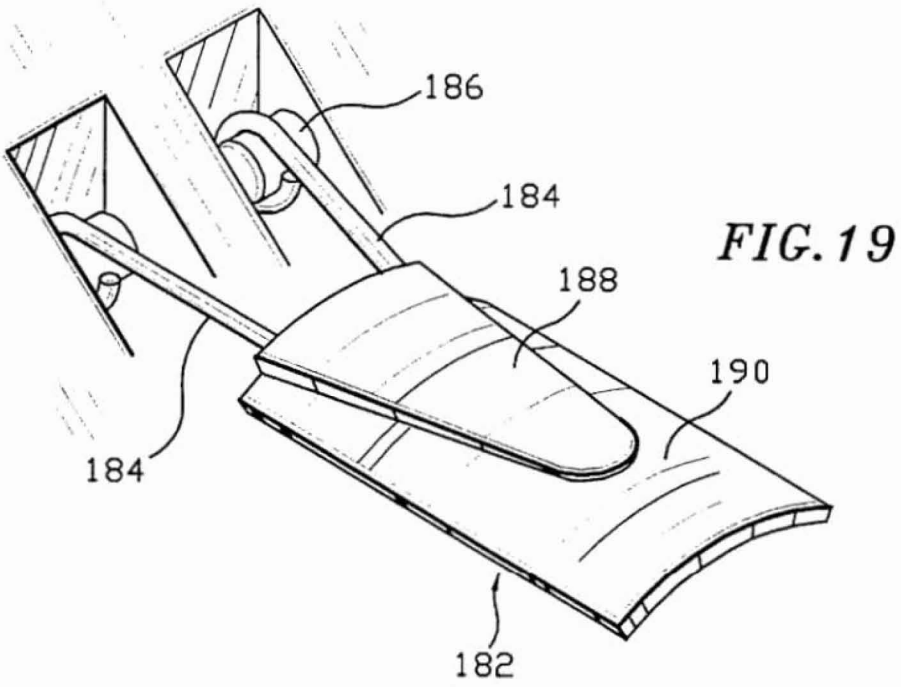


FIG. 19

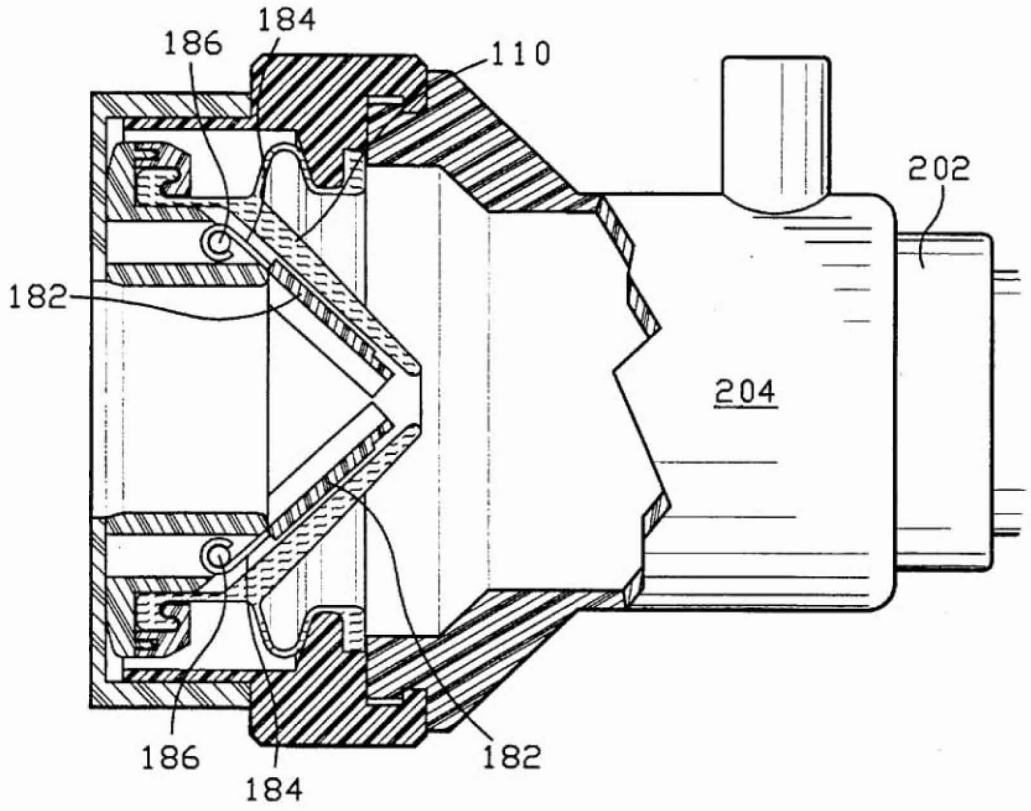


FIG.20

VALVE SYSTEM FOR CANNULA ASSEMBLY

BACKGROUND

1. Technical Field

The present disclosure relates to valve systems of the type adapted to allow the introduction of a surgical instrument into a patient's body. In particular, the disclosure relates to a valve system to be used in combination with a cannula assembly where the cannula assembly is intended for insertion into a patient's body and an instrument is inserted into the patient's body through the cannula.

2. Background Of Related Art

Laparoscopic procedures are performed in the interior of the abdomen through a small incision, e.g., through narrow endoscopic tubes or cannulas inserted through a small entrance incision in the skin. Minimally invasive procedures are performed elsewhere in the body, e.g., in the chest, and are often generally referred to as "endoscopic" procedures. Minimally invasive or endoscopic procedures generally require that any instrumentation inserted into the body be sealed, i.e. provisions must be made to ensure that gases do not enter or exit the body through the endoscopic incision as, for example, in surgical procedures in which the surgical region is insufflated. Moreover, endoscopic procedures often require the surgeon to act on organs, tissues, and vessels far removed from the incision, thereby requiring that any instruments used in such procedures be relatively long and narrow.

For such procedures, the introduction of a tube into certain anatomical cavities such as the abdominal cavity is usually accomplished by use of a system incorporating a trocar and cannula assembly. A cannula assembly is formed of a cannula attached to a cannula housing which generally includes valve assembly adapted to maintain a seal across the opening of the valve assembly both with and without an instrument inserted therethrough. Since the cannula is in direct communication with the internal portion of the valve assembly, insertion of the cannula into an opening in the patient's body so as to reach the inner abdominal cavity should be adapted to maintain a fluid tight interface between the abdominal cavity and the outside atmosphere.

Since minimally invasive surgical procedures in the abdominal cavity of the body generally require insufflating gases to raise the cavity wall away from vital organs, the procedure is usually initiated by use of a Verres needle through which a gas is introduced into the body cavity. The gas provides a slight pressure which raises the wall surface of the peritoneum away from the vital organs thereby providing an adequate region in which to operate. Thereafter, a trocar assembly which includes a cannula and a trocar or obturator is inserted within the cannula to puncture the peritoneum, i.e. the inner lining of the abdominal cavity wall. The obturator is removed and laparoscopic or endoscopic surgical instruments may then be inserted through the cannula to perform surgery within the abdominal cavity. The cannula may also be utilized for introducing tubes into the body as for drainage purposes, for specimen removal, for diagnostic evaluations, or the like.

In view of the need to maintain the atmospheric integrity of the inner area of the cavity, a valve assembly for a cannula which permits introduction of an obturator and a wide range of surgical instruments and which maintains the atmospheric integrity of the inner area of the cavity is desirable. Generally, in the context of insufflatory, minimally invasive surgical procedures, cannula assemblies include structure(s) that two sealing requirements. The first requirement is to

provide a substantially fluid tight seal when an instrument is not present in the cannula. The second requirement is to provide a substantially fluid tight seal when an instrument is being introduced into or already is present in the cannula. In this regard, there have been a number of attempts in the prior art to provide such sealing requirements.

U.S. Pat. No. 4,655,752 to Honkanen et al. teaches a cannula including a housing and first and second seal members. The first seal member is conically tapered toward the bottom of the housing and has a circular opening in its center, while the second seal is conically tapered and cup shaped. The second seal includes at least one slit to allow for the passage of instruments.

U.S. Pat. No. 4,929,235 to Merry et al. teaches a self-sealing catheter introducer having a sealing mechanism to prevent blood or fluid leakage. The sealing mechanism includes a planar sealing element having a slit and a conical sealing element. The sealing elements are each adapted to surround a tube.

U.S. Pat. Nos. 4,874,377 and 5,064,416 to Newgard et al. relate to a self-occluding intravascular cannula assembly in which an elastomeric valving member is positioned transversely to a housing and is peripherally compressed to cause displacement, distortion and/or rheological flow of the elastomeric material. A frustoconical dilator projection cooperates with the elastomeric valving member in moving the valving member to a non-occluding position.

U.S. Pat. No. 5,300,033 to Miller suggests a valve construction including an elastic body having a cylindrical wall with first and second walls formed integrally with the cylindrical wall. The second wall includes a slit to permit passage of a surgical instrument and first and second leaflets which define the slit. The leaflets are thicker in cross section to provide an additional closing force at the slit.

Cannula assemblies have also been developed with a series of resilient sealing elements having a central aperture, e.g., commonly assigned application Ser. Nos. 07/874,291, filed Apr. 24, 1992 and 07/873,416, filed Apr. 24, 1992. Upon insertion of an instrument, the sealing elements resiliently receive and form a seal about the instrument. Upon withdrawal of the instrument, a fluid tight seal is provided by the internal sealing elements.

A disadvantage of several known valve systems for cannulas concerns the difficulty encountered in inserting and advancing the surgical instrument through the valve unit. In particular, since known elastomeric seal members are designed to form and maintain a fluid tight seal about the instrument, the aperture or slit within the seal through which the instrument is passed is of relatively small or narrow dimension. Further, portions of the valve member defining the aperture are generally thick in cross-section to provide a sufficient closing force of the seal about the instrument. see, e.g., U.S. Pat. No. 5,300,033. As a consequence of these design considerations, the level of force needed to insert and advance the instrument through the seal aperture is increased, thereby requiring awkward maneuvering on the surgeon's behalf to appropriately position the instrument for the desired surgery. Moreover, known valve systems are generally ineffectual in accommodating instruments of differing diameter while maintaining acceptable insertion forces and facilitating the range of desired surgical manipulations, e.g., angular instrument movements and specimen removal.

Accordingly, the present invention obviates the disadvantages of the prior art by providing a valve unit or assembly for a cannula assembly, which is capable of forming and

maintaining a tight seal about instruments of varying diameters inserted through the cannula and which incorporates structure to enhance and facilitate passage of the instrument through the valve unit.

SUMMARY

Generally stated, the present disclosure is directed to a valve assembly for sealed reception of an elongated object. The assembly includes a valve body having at least one opening configured and dimensioned to permit entry of an elongated object and defining a central longitudinal axis, an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body whereby the aperture is configured and dimensioned such that insertion of the object into the aperture causes the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner, and at least one elongated guard member disposed within the valve member in supporting contact with the inner surface thereof and positioned to engage the elongated object upon at least partial insertion of the elongated object into the valve body. The guard member includes at least a first substantially rigid portion adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member and a second portion having less rigidity than the first portion of the guard member to enhance passage of the elongated object through the valve body. The second portion of the guard member may be positioned adjacent the aperture of the seal member to provide an interface between the guard member and the seal member to thereby protect the portions of the seal member defining the aperture from engagement with the elongated object.

The preferred guard member is a monolithically formed single piece unit wherein the first portion of the guard member defines a cross-sectional dimension which is greater than the cross-sectional dimension of the second portion, thus providing the more rigid characteristic to the first portion.

In a preferred embodiment, the valve assembly includes a valve housing having a longitudinal opening configured and dimensioned to permit entry of an elongated object, an elongated resilient seal member at least partially positionable within the valve housing and defining an aperture to permit entry of the elongated object therein in a substantially fluid tight manner and a plurality of guard members disposed within the seal member and concentrically arranged about a central longitudinal axis defined by the valve housing. The plurality of guard members are positioned to engage the elongated object upon insertion of the elongated object within the valve housing and are adapted to be radially displaced upon introduction of the elongated object to engage portions of the seal member defining the aperture to expand the aperture. Each guard member possesses an end portion of less rigidity than the remaining portion(s) of the guard member wherein the end portion of less rigidity reduces the force required to advance the elongated object through the valve housing.

The guard members of this embodiment are preferably pivotally mounted to a generally annular guard mount and extend generally longitudinally within the seal member. The end portions of the guard members overlap to form an iris-like arrangement. Upon entry of the elongated object, the guard members simultaneously pivot outwardly to uniformly engage and stretch or dilate the inner surfaces of the seal member to open or expand the aperture.

The elongated seal member of the valve assembly preferably includes a central frusto-conical portion which accommodates the guard members and a circumferential portion. The circumferential portion includes a bellows structure which is engageable with the valve housing and dimensioned to maintain a substantially fluid tight seal with the valve housing upon manipulation of the elongated object within the aperture. In particular, the bellows structure enables the seal member to float within the valve housing while maintaining a fluid tight seal about the elongated object and within the housing.

The valve assembly is intended to be used in combination with a cannula including a cannula housing and a cannula sleeve extending distally from the cannula housing and is preferably detachably connectable to the cannula housing. The cannula housing may include a valve member disposed therein which is moveable between a substantially closed position in the absence of an instrument to an open position in the presence of an instrument.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described hereinbelow with reference to the drawings wherein:

FIG. **1** is a perspective view with parts separated of a trocar assembly cannula assembly and valve assembly constructed according to the principles of the present disclosure;

FIG. **2**A is an exploded perspective view with parts separated of the valve assembly of FIG. **1**;

FIG. **2**B is a perspective view of the valve assembly in the assembled condition;

FIG. **3** is an enlarged perspective view of the resilient seal member of the valve assembly of FIG. **2**A;

FIG. **4** is a cross-sectional view of the seal member of FIG. **3**;

FIG. **5** is an enlarged perspective view of the guard mount of the valve assembly of FIG. **2**A illustrating the guard members supported by the guard mount;

FIG. **6** is a top plan view of the guard mount of FIG. **5** with the guard elements disassembled from the guard mount;

FIG. **7** is a cross-sectional view taken along the lines **7**—**7** of FIG. **6**;

FIGS. **8**A–**8**C are cross-sectional views of a portion of a single guard mount illustrating a preferred method for pivotally connecting a guard element to the guard mount;

FIG. **9** is an alternative two-piece guard mount to be incorporated in the valve assembly of FIG. **2**A and illustrates a preferred method for mounting the guard elements to the guard mount;

FIG. **10** is a side plan view in partial cross-section of the cannula housing and the valve assembly detachably mounted the cannula housing of the cannula assembly;

FIG. **11** is an enlarged cross-sectional view illustrating the valve assembly and the cannula housing;

FIG. **12** is a view similar to FIG. **10** illustrating the introduction of an elongated object into the valve assembly and cannula assembly;

FIG. **13** is a view similar to FIG. **11** illustrating sealing engagement of the resilient seal member of the valve assembly with the elongated object;

FIG. **14** is a view similar to FIG. **12** illustrating the adaptability of the valve assembly to radial movement of the elongated object in the cannula assembly;

FIG. **15** is a view similar to FIG. **13** further depicting the adaptability of the valve assembly to accommodate for radial movement of the elongated member;

FIG. **16** is a side plan view in partial cross-section of an assembled trocar and cannula assembly in combination with the valve assembly of FIG. **2**A;

FIG. **17** is an enlarged isolated view of the mechanism for detachably securing the trocar assembly relative to the valve assembly;

FIG. **18** is an enlarged perspective view of an alternative guard mount to be incorporated in the valve assembly of FIG. **2**A;

FIG. **19** is an enlarged perspective view of a single guard element of the guard mount of FIG. **18** illustrating the mounting of the guard element to the guard mount; and

FIG. **20** is a cross-sectional view of the valve assembly with the guard mount of FIG. **18**.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT(S)

The present disclosure contemplates the introduction into a person's body of all types of surgical instruments including clip appliers, graspers, dissectors, retractors, staplers, laser fibers, photographic devices, endoscopes and laparoscopes, tubes, and the like. All such objects are referred to herein as "instruments".

Referring initially to FIG. **1**, there is illustrated the novel valve assembly **100** constructed in accordance with the principles of the present disclosure and intended to be used in combination with a conventional trocar assembly consisting of cannula assembly **200** and trocar assembly **300**.

The valve assembly of the present disclosure, either alone or in combination with a valve unit/seal assembly internal to cannula **200**, and either integral with or detachably mounted to cannula **200**, provides a substantial seal between a body cavity of a patient and the outside atmosphere, both, during and subsequent to insertion of an instrument through the cannula. Moreover, the valve assembly **100** of the present disclosure is capable of accommodating instruments of varying diameter, e.g. from 5 mm to 12 mm, by providing a gas tight seal with each instrument when inserted. The flexibility of the present valve assembly greatly facilitates endoscopic surgery where a variety of instruments having differing diameters are often needed during a single surgical procedure.

The valve assembly is preferably detachably mountable to the proximal end of cannula **200** disclosed herein. Thus, the surgeon can remove the valve assembly **100** from the cannula assembly **200** at any time during the surgical procedure and, similarly, mount the assembly **100** to the cannula when desired to provide a sealing engagement with an instrument to be inserted through the cannula. In addition, the valve assembly **100** may be readily adapted to be mounted to conventional cannulas of differing structures. The detachability of valve assembly **100** from cannula **200** facilitates specimen removal through cannula **200** and reduces the profile of cannula **200** when valve assembly is not needed for the surgical procedure.

Referring now to FIGS. **2**A and **2**B, the novel valve assembly of the present disclosure will be discussed in detail. As shown in the exploded view of FIG. **2**A, Valve assembly **100** includes end cap **102**, stabilizer plate **104**, guard mount **106**, guard holder **108**, seal element **110** and seal housing **112**. End cap **102**, stabilizer plate **104** and seal housing **112** form the outer valve body of the assembly, which houses the sealing and dilating components of the system, i.e., guard mount **106**, guard holder **108** and seal element **110**.

End cap **102** is generally cylindrically-shaped and includes a proximal end portion **103** defining a diameter which is less than the diameter of the remaining portion of the end cap and an inner peripheral ledge **114** which supports stabilizer plate **104**. Guard holder **108** is ring-like in configuration and includes inner and outer peripheral grooves **109**, **111** respectively formed in its proximal face. Grooves **109**, **111** assist in retaining guard mount **106** within seal **110**. Seal housing **112** includes central opening **116**, a proximal cylindrical portion **118** and a distal outer flange **120** having a scalloped surface to facilitate handling thereof. Cylindrical portion **118** is received within end cap **102** when the valve assembly is fully assembled to enclose the sealing components. The distal end face of seal housing **112** includes a peripheral groove **122** and two opposed rib portions **124** extending radially inwardly adjacent the groove **122**. Groove **122** and rib portions **124** assist in mounting valve assembly **100** to cannula **200** as will be appreciated from the description provided below. The distal end face of seal housing **112** also includes a second groove **126** adjacent opening **116** for accommodating a portion of seal **110**.

Referring now to FIGS. **2**A, **3** and **4**, sealing element **110** includes a generally frusto-conical interior portion **128** defining aperture **130**, a circumferential flange portion **132** at its proximal end and circumferential bellows structure **134** disposed adjacent the distal end of the seal **110** and having distal outer flange portion **135**. Seal **110** is fabricated from an elastomeric material such as synthetic or natural rubber which is preferably sufficiently resilient to accommodate and provide a fluid seal with instruments of varying diameters inserted through aperture **130**, e.g., instruments ranging in diameter from about 5 mm to about 12 mm, and sufficiently resilient to flex at bellows structure **134** to accommodate manipulation of instrumentation inserted through aperture **130**. A plurality of generally longitudinally extending ribs **136** are disposed along the inner surface of frusto-conical portion **128**. Ribs **136** provide additional support to seal **110** and are intended to engage the elongated instrument upon insertion thereof through the seal to minimize the potential of damage such as cutting or tearing of the seal by the distal end of the instrument. Flanges **132**, **135** function in mounting seal **110** to the valve body as will be appreciated from the following description. Seal **110** may also include at least one aligning projection **133** extending from its proximal face to assist in mounting the seal to guard mount **106**. Preferably seal **110** includes three projections **133**.

Referring now to FIG. **2**A, in conjunction with FIGS. **5**–**7**, guard mount **106** of valve assembly **100** will be discussed. Guard mount **106** includes an annular base portion **138** and a plurality of guard elements **140** pivotally mounted relative to the base portion. Base portion **138** defines a central opening **142** which is variably dimensioned to permit passage of an instrument therethrough, as discussed below, and an outer circumferential flange **144** at its proximal end. Circumferential flange **144** includes a circumferential lip **147** and three apertures **145** correspondingly dimensioned to accommodate the three aligning projections **133** extending from seal **110** (FIG. **2**A).

Guard mount **106** also includes a plurality of slots **146** (FIG. **6**) defined in the outer wall of base portion **138** for accommodating the proximal ends of guard elements **140**. Slots **146** are equidistantly disposed about base portion **138** and extend generally longitudinally from a position inter-

mediate the proximal and distal ends of the guard mount **106** through the distal end face of the base portion **138**.

Each guard element **140** includes a finger-like portion **148** and an outer flap portion **150** connected at distal end of finger portion **148**. Flap portion **150** may be joined to finger portion **148** in a variety of manners, e.g., adhesive or insert molding, or flap portion **150** and finger portion **148** may preferably be an integrally molded component. Finger portions **148** are accommodated within respective slots **146** in guard mount **106** and include a pair of opposed projecting members **152** extending outwardly from their proximal ends (FIG. **6**). Projecting members **152** serve in pivotally mounting guard elements **140** to guard mount **106**.

As best shown in FIGS. **7** and **8A–8C**, the outer flap **150** of each guard element **140** defines first and second portions **154**, **156** of varying thicknesses. The first or proximal portion **154** has a cross-sectional dimension or thickness which is greater than the thickness of the second or distal portion **156** of the outer flap **150**. Preferably, first portion **154** is from about two to about three times thicker in cross-sectional dimension than second portion **156**. This dimensional ratio translates to second portion **156** being about two to three times more flexible than first portion **154**, assuming the same material of construction. Such dimensioning of outer flap **150** ensures that guard elements **140** are sufficiently rigid to cause stretching of the seal surface portions **110** defining seal aperture **130** to thereby increase the dimension of the aperture **130** and facilitate insertion of the instrument therethrough and, in addition, provide sufficient flexibility to minimize the force required to advance the instrument through the guard element and seal arrangement.

More specifically, by the strategic dimensioning of the guard elements **140** the following characteristics are present: 1) the finger portion **148** in combination with the relative thick first portion **154** of outer flap **150** provides a substantially rigid section of the guard element **140**, which section is capable of sufficiently engaging the inner frustoconical surface **128** of seal **110** and enlarging the aperture **130** of the seal by displacing seal portions defining the aperture **130** radially outwardly; and 2) the relatively thin and less rigid, i.e., relatively, flexible second portion **156** of outer flap **150** reduces the force required to pass the instrument through the guard mount and seal arrangement and, also, minimizes the risk of damage to the inner surface of the seal by providing a protective interface between the instrument and the inner wall. Inasmuch as guard elements **140** are pivotally mounted to guard mount **106**, as an instrument contacts outer flap **150** along its length, i.e., both along first portion **154** and second portion **156**, outer flap **150** is pivoted relative to projecting members **152** against seal **110** in dilating contact therewith.

Guard elements are fabricated from a suitable material such as high density polyethylene, and, as noted above, are preferably monolithically formed by injection molding techniques to define a single element. It is also possible for the finger portion **148** and flap portion **150** of guard element **140** to be individually formed and subsequently connected by adhesives or the like.

Referring now to FIGS. **6**, **7**, and **8A–8C**, the mounting of each guard element **140** to guard mount **106** will be discussed in detail. Each guard element **140** is individually mounted within a slot **146** in base portion **138** of guard mount **106** by inserting the proximal finger portion **148** within the base of the slot as shown in FIG. **8A** and advancing the guard element into the slot such that the opposed projecting members **152** snap into correspondingly dimensioned grooves **158** (FIGS. **8A–8C**) formed in portions **160** of base **138** adjacent each slot.(see FIG. **6**) FIG. **8B** depicts the projecting members **152** locked into grooves **158**. Thereafter, each guard element **140** is pivoted upwardly to its appropriate position as shown in FIG. **8C**.

FIG. **9** illustrates an alternative guard mount **162**, and assembly method therefor, to be incorporated in the valve assembly **100** of the present disclosure. In accordance with this embodiment, guard mount **162** includes lower half section **164** and upper half section **166** positionable on the lower half section. Guard mount **162** is substantially identical in configuration to the guard mount **106** described in connection with FIGS. **5–7** except that this guard mount **162** is provided with a radial groove **168** which is disposed adjacent each slot **170**. In further accordance with this embodiment, the guard elements **140** are simultaneously integrally molded to define a single unit as shown in FIG. **9**. In the single molded unit, each guard element **140** is appropriately positioned and oriented to be placed within a corresponding slot **170** within the lower half section **164** of guard mount **162**, i.e., during assembly, the single unit is positioned against the lower section **164** with guard elements **140** being received within the slot portions **170**. Thereafter, the central molded portion **172** and the stems **174** interconnecting the guard elements **140** and the central molded portion are removed leaving the guard elements **140** within their respective slots. It is to be appreciated that a portion of stem **174** connected to each guard element **140** may remain after removal of the central portion **172**. This stem portion is received within radial groove **168** in assembly and serves to resist any tendency of the guard element **140** to rotate out of its respective slot **170**. Once the guard elements **140** are positioned within their respective slots **170** with the opposed projections **152** in place within grooves **176** in guard mount **162**, the upper section **166** of the guard mount is attached to the lower section by adhesives, spot welding or the like. The assembled guard mount **160** and guard elements **140** operate in a similar manner to that described in connection with mount **106** of FIG. **5**.

Referring again to FIG. **5**, the guard elements **140** in their fully assembled position may be oriented define a generally frusto-conical configuration so as to be positioned within the frusto-conical portion **128** of seal **110**. Preferably, guard elements **140** are arranged in overlapping relation, i.e., whereby outer flap portions **150** of adjacent guard elements **140** overlap each other to define a general iris-like arrangement of the guard elements. This desired arrangement is achieved by pivoting a first guard element **140** inwardly and thereafter sequentially pivoting the remaining guard elements onto each other. Once all the guard elements **140** are in a fully pivoted position, the leading edge of the outer flap portion **150** of the last pivoted guard element **140** is tucked under the trailing edge of the flap portion **150** of the first pivoted guard element to provide the arrangement shown in FIG. **5**.

Referring now to FIGS. **2A–2B**, in conjunction with FIGS. **10–11**, the assembling of the components of valve assembly **100** will be discussed in detail. Although in FIGS. **10** and **11** the valve assembly **100** is shown already mounted to cannula **200**, it is to be appreciated that generally valve assembly **100** is first assembled as a single unit and then mounted to the cannula. The mounting of valve assembly **100** to cannula **200** will be discussed below. Stabilizer plate **104** is positioned within end cap **102** such that the plate **104** rests on inner peripheral ledge **114** defined within the end cap **102**. Thereafter, guard holder **108** is positioned over the proximal flange **132** (FIG. **4**) of seal **110** whereby the inner

peripheral groove **109** of the guard holder **108** receives and accommodates the proximal flange **132** of the seal **110**. Thereafter, seal **110** and guard holder **108** are positioned over guard mount **106** (FIG. **5**) and advanced onto the mount until proximal flange **132** of the seal is abutting circumferential flange **144** of the mount **106** and aligning projections **133** are received within apertures **139** formed in the circumferential flange **144** as shown in cross-section in FIG. **11**. In this position, the circumferential lip **147** on circumferential flange **144** (FIG. **5**) is received within the outer groove **111** of guard holder **108**.

Assembly is continued by placing the assembled seal **110**, guard holder **108** and guard mount **106** subassembly against stabilizer plate **104** which is positioned against ledge **114** within end cap **102**. Thereafter, seal housing **112** is positioned over the entire unit with the cylindrical wall **118** of the seal housing being received within the cylindrical wall of end cap **102**. In this assembled condition, the distal end portion of the cylindrical wall of end cap **102** is received within an annular space defined between distal flange **120** of seal housing **112** and cylindrical wall **118** of seal housing **112** and retained therein by a friction or snap fit, thus retaining the valve assembly in a fully assembled condition. It is to be noted that in the assembled condition the distal flange **135** of bellows structure **134** of seal **110** is positioned over the distal face of seal housing **112** wherein the flange **135** is received within second circumferential groove **126** of the seal housing.

The valve assembly **100** now in its fully assembled condition can be mounted to cannula **200**. Referring to FIGS. **1**, **10** and **11**, cannula **200** is part of a trocar assembly and includes a cannula sleeve **202** and a cannula housing **204** mounted on one end of the sleeve. Sleeve **202** defines a cannula passage in its interior and may be formed of stainless steel or other rigid materials such as polymeric materials or the like.

Cannula housing **204** is rigidly secured to the proximal end of cannula **202** and defines a longitudinal opening for reception and passage of an elongated surgical instrument. The proximal end portion of the cannula housing **204** defines a generally circular cross-section and possesses diametrically opposed leg portions **206**. A cannula seal **208** fabricated from a resilient material, e.g., rubber, is positioned within the interior of cannula housing **204**. Seal **208** includes a circumferential flange portion **210** which rests on a correspondingly dimensioned circumferential ledge **212** within cannula housing **204**. Seal **208** generally defines a duck bill shape having two planar tapering portions **214** which intersect at their distal ends to define abutment face **216**. The planar tapering portions **214** may each include one or more inwardly directed, longitudinally oriented ribs to facilitate instrument passage. Abutment face **216** permits passage of the elongated object through the seal **208**, but in the absence of an instrument, and particularly when cannula **202** is inserted into an insufflated body cavity, abutment face **216** forms a gas-tight seal that isolates the insufflated cavity from the ambient surroundings. Seal **208** also includes at least one, preferably two, reinforcing ribs **215** to stabilize the seal. Ribs **215** are positioned to engage the instrument to guide the instrument through slits **216** and prevent piercing of the seal **208** by the tip of the instrument.

Cannula **200** also includes a stabilizing plate **218** (FIG. **1**) which is positioned against the flange portion **210** of seal **208** to provide support for the seal during introduction and withdrawal of an elongated instrument. Stabilizing plate **218** includes two diametrically opposed extensions **220** (FIG. **1**) which are received within the correspondingly dimensioned leg portions **206** of the cannula housing **204**. In the preferred embodiment, stabilizing plate **218** is securely attached to cannula housing **204** at contact points along the extensions of the respective components by spot welding, adhesives or the like. Stabilizing plate **218** also includes a partial external annular rib or thread **222** (FIG. **11**) adjacent its proximal end, the function of which will be appreciated from the description below.

A stop cock valve **224** may be incorporated as part of cannula housing **204** to permit the passage of insufflation gases through the cannula and into the body cavity. A suitable valve for this purpose is available from the Burron OEM Division of B. Braun Medical, Inc. (Model No. 55401022).

Referring still to FIGS. **1**, **10** and **11**, the mounting of valve assembly **100** to cannula housing **204** will be discussed. The assembled valve assembly **100** is detachably mounted adjacent stabilizing plate **218** with the partial annular thread **222** of the stabilizing plate **218** being received within the peripheral groove **122** (FIG. **2***a*) defined in the distal face of seal housing **112**. The valve assembly **100** is rotated to cause engagement of the radially inwardly projecting rib portions **124** adjacent groove **122** with the partial annular thread **222** to releasably lock the valve assembly **200** to the cannula housing. Other means for detachably connecting the valve assembly **100** to cannula housing **204** can be readily determined by one skilled in the art such as screw threads, adhesives, bayonet locking, and the like.

Referring now to FIGS. **12** and **13**, an elongated object such as a surgical instrument, identified generally as numeral **400**, may be inserted through the valve assembly **100** and into the cannula **200** to perform the desired diagnostic procedure and/or surgery. As the surgical instrument enters the valve assembly, the tip of the surgical instrument is engaged by the guard elements **140**. Upon further advancement of the surgical instrument, the guard elements **140** are pivoted radially outwardly to bias the seal member in an outward direction thereby stretching the seal portions defining the aperture **130** and increasing the dimension of the aperture to the degree necessary to accommodate instrument **400**. As previously stated, the particular dimensioning of the guard elements **140**, i.e. the rigid section in combination with the more flexible outer portion, ensures adequate stretching of the seal element **110** while also permitting relatively easy passage of instrument **400** through the valve assembly. In addition, the overlapping arrangement of the outer flap portions **150** of the guard elements facilitate dilation of the seal aperture and minimize the potential for the distal end of the instrument to contact and pierce the resilient material of the inner surface of seal **110** by providing an interface between the guard elements and the seal. The resilient seal member **110** sealingly engages to form a substantial fluid-tight seal about the surgical instrument and a fluid tight seal within the valve housing and the external atmosphere. The instrument **400** is advanced through the cannula **200** whereby the duckbill seal of the cannula also spreads to allow passage of the instrument. Once positioned within the valve assembly **100** and cannula **200**, the surgical instrument may be maneuvered about the internal body cavity.

As shown in FIGS. **14–15**, the valve assembly permits limited unencumbered movement of the instrument in a radial direction (relative to the centerline of cannula **202**) while still maintaining an adequate seal about the instrument. This is due to the strategic spacing of the inner valve components, i.e., guard mount **106** and seal **110**, relative to

the valve body, i.e., end cap **102** and seal housing **112**, and the bellows structure **134** of the seal **110**. In particular, the bellows structure **134** provides sufficient flexibility to permit the valve components to "float" within the valve housing while still preserving the integrity of the seals established about the surgical instrument and within the cannula assembly. Thus, manipulation of the instrument in any direction, either longitudinally or radially, to he extent permitted by the rigid housings and cannula, will not effect the seal, since the resilient material of the seal element and the bellows structure will conform to the movements of the instrument and assume a desired shape necessary to retain sealing contact with the instrument.

Referring now to FIGS. **1**, **16** and **17**, the novel valve assembly **100** may be used with a trocar of the type described in the figures. This trocar **300** is disclosed in U.S. patent application Ser. No. 07/957,673 filed Oct. 7, 1992, the contents of which are incorporated herein by reference, and includes trocar housing **302**, an obturator **304** extending distally from the housing **302** and having piercing tip **306** and a stationary or tube **308** which houses the obturator when it is unarmed. Obturator **304** is advanced beyond the distal end of cannula **202** to expose the obturator tip **306** by advancing actuating button **310**. This trocar **300** also includes a locking hinge **312** within the trocar housing **302** which is actuated upon depression of the actuating lever **310**.

The trocar housing **302** may be longitudinally fixed relative to valve assembly **100** and cannula **200** by inserting the trocar within the aperture defined in end cap **102** of the assembly **100**, advancing the trocar through the valve assembly and into cannula sleeve **202**, and advancing actuating button **310**. The proximal end portion **103** of end cap **102** defines a smaller diameter than the remaining or main portion of the cap **102** (See also FIG. **11**) and, thus, defines a circumferential locking ledge **105** at its intersection with the main cap portion. Once the trocar **300** is appropriately positioned in the cannula **202**, the obturator **304** and obturator tip **306** are advanced by advancing actuating button **310** which causes corresponding radial outward movement of the hinge member **312** and engagement of the hinge member **312** with the circumferential locking ledge **105** of the end cap **102** as shown in FIG. **17** to detachably secure the trocar housing **302** relative to the valve assembly **100** and cannula assembly **200**. Because locking ledge **105** extends circumferentially, trocar housing **302** may be detachably secured to valve assembly **100** at any relative angular orientation. The valve assembly is capable of forming a seal about the trocar in the same manner described above.

In operation, the distal end of the trocar **300** having the obturator tip **306** in an exposed position beyond the cannula **202** of the cannula assembly **200** is placed against the skin at the body cavity region, and pressure is exerted on the assembly against the skin. This pressure causes the obturator tip **306** to enter the skin and underlying tissue. Once the tip has penetrated the tissue and has entered the cavity, the tip automatically retracts into the cannula as described in U.S. Pat. No. 5,116,353, and the trocar can be withdrawn from the cannula assembly to permit introduction of surgical instruments such as forceps, graspers, or the like through the remaining cannula **200**. Alternatively, a trocar having a spring biased protective sleeve such as is described in U.S. Pat. No. 4,601,710 or a conventional trocar which does not include a safety mechanism may be employed through valve assembly **100** and cannula assembly **200**. It is to be appreciated that upon removal of the trocar **300** from the cannula **200**, the duck bill **208** closes automatically to preserve the state of insufflation of the peritoneum. In particular, the pressure exerted by the insufflation gases through the cannula sleeve **202** biases the planar portions **214** (FIG. **14**) of the duck bill **208** towards each other thereby closing the abutment face **216** defined at the juncture of the two planar portions.

FIGS. **18–20** depict an alternate guard mount **180** to be incorporated in the valve assembly of the present disclosure. In accordance with this embodiment, the guard elements **182** are mounted to the guard mount via two rods **184** which are connected at their first ends to the guard element **182** via insert molding techniques and at the second ends to a pivot rod **186** within the guard mount. The guard elements **186** pivot in a similar manner to that described in connection with the embodiment of FIG. **1** and possess a rigid section as defined by the finger portion **188** and a more flexible outer section as defined by outer flap **190**.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the invention, but merely as an exemplification of a preferred embodiment thereof. Those skilled in the art will envision other possible variations that are within the scope and spirit of the invention as defined by the claims appended hereto.

What is claimed is:

1. Valve assembly for sealed reception of an elongated object, which comprises:

a) valve body having at least one opening configured and dimensioned to permit entry of an elongated object and defining a central longitudinal axis;

b) an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body, the aperture being configured and dimensioned such that insertion of the object into the aperture causes the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner; and

c) a plurality of elongated guard members disposed within the seal member in contact with the inner surface thereof, the guard members positioned to engage the elongated object upon at least partial insertion of the elongated object into the valve body, each of the guard members including at least a first substantially rigid portion and a second portion having less rigidity than the first portion, each guard member adapted to be displaced relative to the longitudinal axis to facilitate expansion of the aperture of the seal member upon entry of the object therein.

2. The valve assembly according to claim **1** wherein the second portion of each guard member is positioned adjacent, but proximal to, the aperture of the seal member to provide an interface between the elongated object and the seal member to thereby protect the resilient material defining the aperture from damage from the elongated object.

3. The valve assembly according to claim **1** wherein each guard member is a monolithically formed integral unit.

4. The valve assembly according to claim **1** wherein the first portion of each guard member defines a cross-sectional dimension which is greater than the cross-sectional dimension of the second portion of the guard member.

5. The valve assembly according to claim **1** wherein each guard member is fabricated from a material selected from the group consisting of high density polyethylene, low density polyethylene, and low density polyethylene with a polytetra fluorethylene additive.

6. A valve assembly for sealed reception of an elongated object, which comprises:

a) a valve housing having a longitudinal opening configured and dimensioned to permit entry of an elongated object;

b) an elongated resilient seal member at least partially positionable within the valve housing and defining an aperture to permit entry of the elongated object therein in a substantially fluid tight manner; and

c) a plurality of guard members disposed within the seal member and concentrically arranged about a central longitudinal axis defined by the valve housing and positioned to engage the elongated object upon insertion of the elongated object within the valve housing, each guard member adapted to be radially displaced during introduction of the elongated object within the valve assembly to engage portions of the valve member adjacent, but proximal to, the aperture to expand the aperture, each guard member having an end portion of less rigidity than the remaining portions of the guard member, the end portion dimensioned to reduce the force required to advance the elongated object through the valve housing.

7. The valve assembly according to claim **6** wherein the proximal end of the seal member includes a circumferential flange.

8. The valve assembly according to claim **7**, further including an annular guard holder disposed about the seal member, the guard holder engagable with the circumferential flange of the seal member and dimensioned to retain the circumferential flange against the annular guard mount to maintain the substantially fluid tight seal of the valve member.

9. The valve assembly according to claim **6** wherein each guard member is pivotally mounted at a proximal end thereof to a generally annular guard mount.

10. The valve assembly according to claim **6** wherein adjacent end portions of the guard members overlap.

11. The valve assembly according to claim **6** wherein the elongated seal member includes a central frustoconical portion defining the aperture and a circumferential portion, the circumferential portion including a bellows structure, the bellows structure engageable with the valve housing and dimensioned to maintain a substantially fluid tight seal with the valve housing notwithstanding manipulation of the elongated object within the aperture.

12. The valve assembly according to claim **6** wherein the seal housing and the valve member define therebetween a space to permit radial movement of the valve member within the valve housing.

13. An assembly for the introduction of elongated objects into the body of a patient while maintaining a substantially fluid tight seal between internal body portions and the outside atmosphere, which comprises:

a) a cannula including a cannula housing and a cannula sleeve extending distally from the cannula housing;

b) a valve assembly mounted to the cannula assembly, the valve assembly including:

i) a valve body having at least one opening configured and dimensioned to permit entry of an elongated object and defining a central longitudinal axis;

ii) an elongated seal member formed of a resilient material and defining an aperture in general alignment with the opening of the valve body, the aperture being configured and dimensioned such that insertion of the object into the aperture causes the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner; and

iii) a plurality of guard members disposed within the seal member and concentrically arranged about a central longitudinal axis defined by the valve body and positioned to engage the elongated object upon insertion of the elongated object within the valve body, each guard member adapted to be radially displaced upon contact with the elongated object to engage the seal member to expand the aperture, each guard member having an end portion of less rigidity than the remaining portions of the guard member, the end portions dimensioned to reduce the force required to advance the elongated object through the valve body; and

c) means for detachably connecting the valve assembly to the cannula housing.

14. The assembly according to claim **13** wherein the cannula housing includes a member disposed therein, the member moveable between a substantially closed position in the absence of an object to an open position in the presence of an object.

15. The assembly according to claim **14** wherein the member is of a duck-bill shape.

16. The assembly according to claim **14** wherein the member of the cannula housing includes at least one longitudinally extending reinforcing rib for providing additional support to the member, the reinforcing rib positioned to engage the elongated object upon insertion therethrough.

17. The valve assembly according to claim **13**, wherein the means for detachably connecting comprises interacting threads.

* * * * *

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United States Patent [19]

Green et al.

[11] Patent Number: 5,304,143

[45] Date of Patent: Apr. 19, 1994

[54] **VALVE SYSTEM FOR INTRODUCING OBJECTS INTO ANATOMICAL BODY PORTIONS**

[75] Inventors: **David T. Green**, Westport; **Henry Bolanos**, East Norwalk, both of Conn.

[73] Assignee: **United States Surgical Corporation**, Norwalk, Conn.

[21] Appl. No.: **992,143**

[22] Filed: **Dec. 17, 1992**

Related U.S. Application Data

[63] Continuation of Ser. No. 711,756, Jun. 7, 1991, Pat. No. 5,180,373.

[51] **Int. Cl.**[5] **A61M 8/00**

[52] **U.S. Cl.** **604/167**; 604/156

[58] **Field of Search** 604/167, 256

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Primary Examiner—Paul J. Hirsch

[57] **ABSTRACT**

A valve assembly adapted for introduction of an elongated object into a patient's body having a first valve formed of a resilient material and defining an aperture for reception of the object, the aperture being configured and dimensioned such that insertion of the object into the aperture will cause the resilient material defining the aperture to resiliently engage the outer surface of the object in a fluid tight manner. A second valve is positioned adjacent and distal of the first valve in general alignment therewith, whereby the second valve defines an aperture in general alignment with the aperture of the first valve, and is formed of a flexible material at least in the region defining the aperture. A pair of manually operable clamps are provided to selectively permit the aperture of the second valve to be opened or closed so as to permit entry of the object such that the object first passes through the first valve and then the second valve prior to entry into the patient's body.

37 Claims, 4 Drawing Sheets

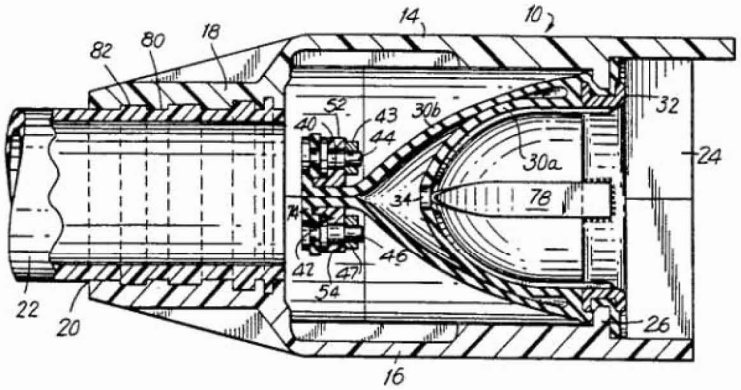

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FIG. 1

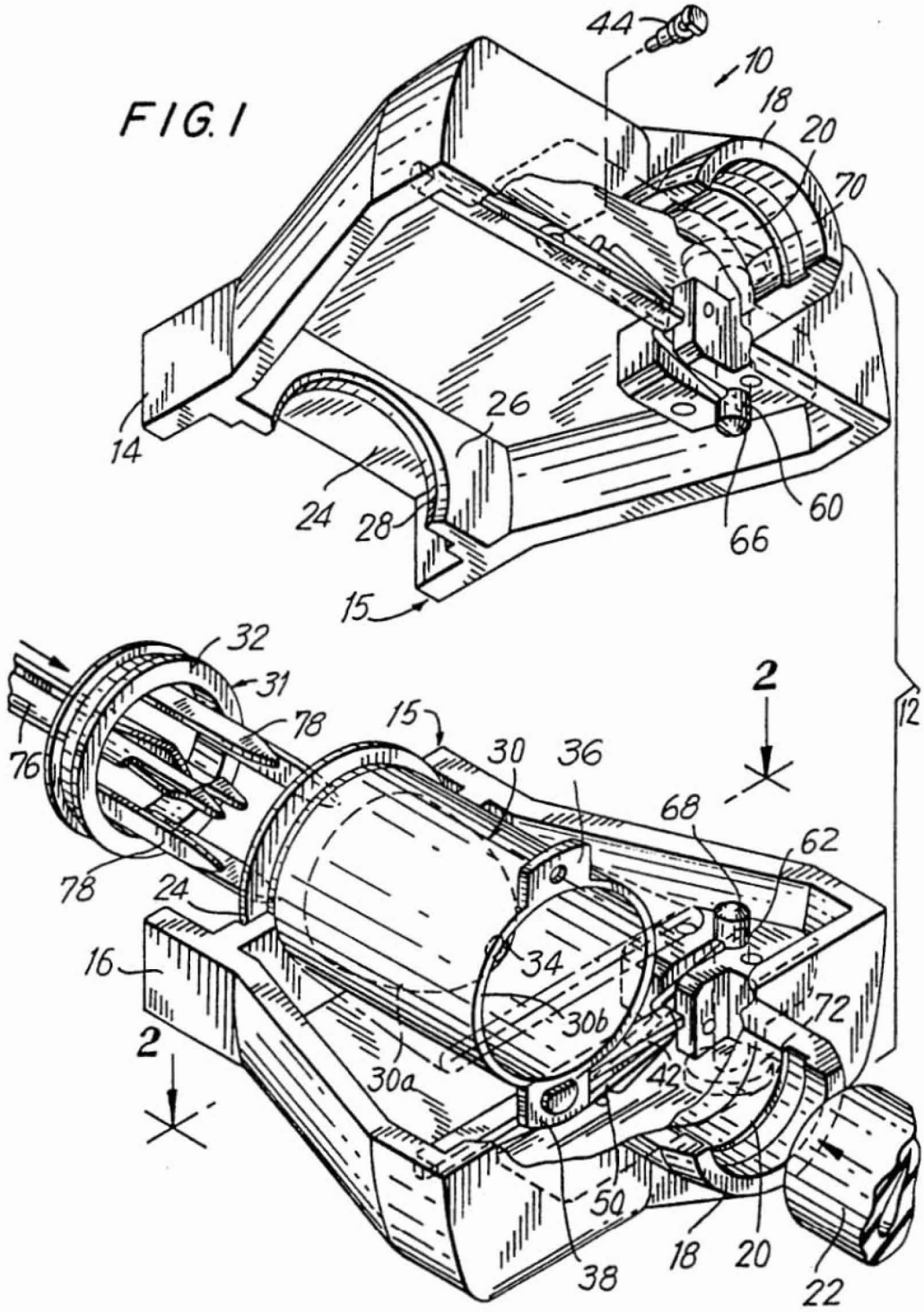
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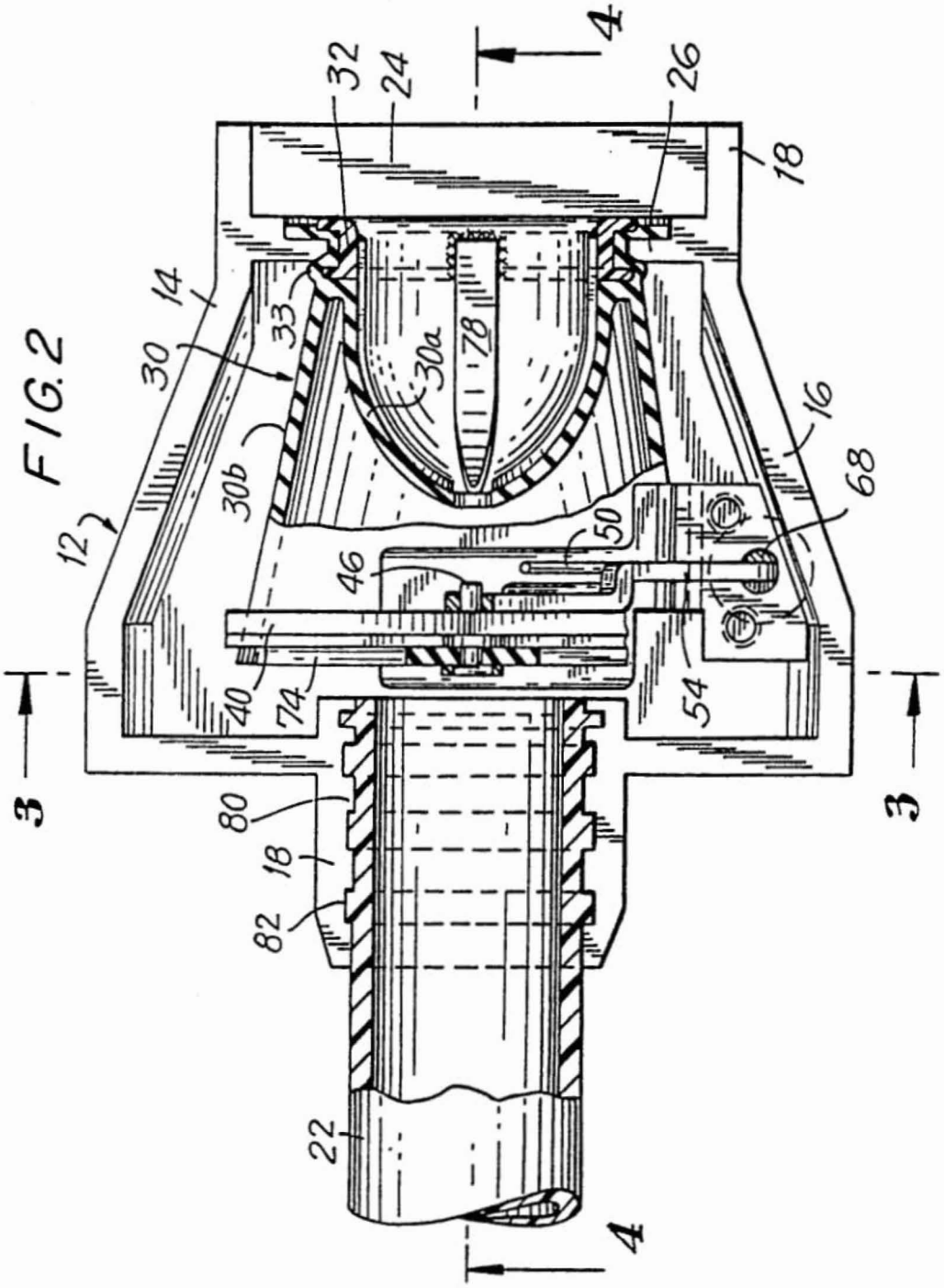
FIG. 2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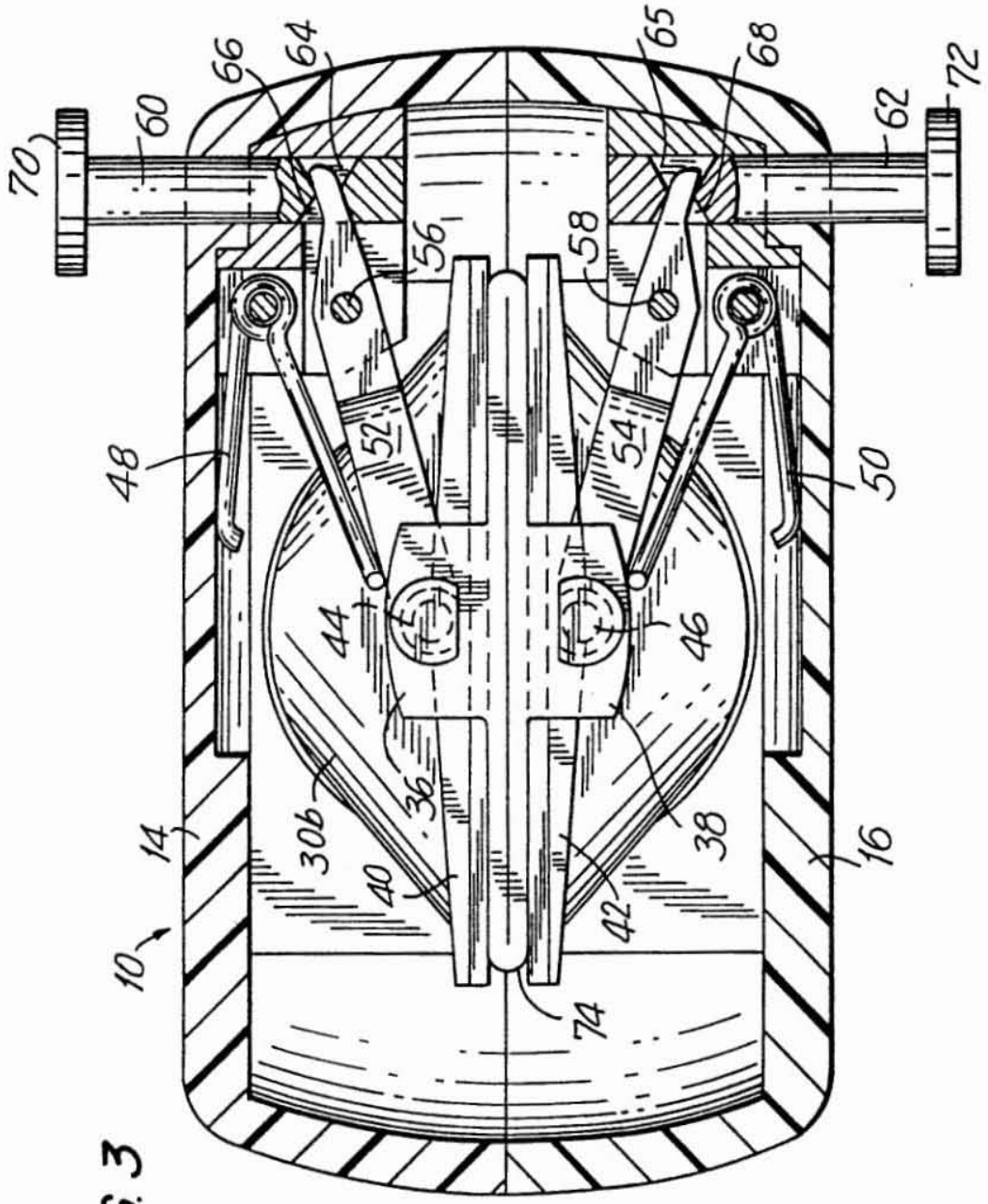
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FIG. 3

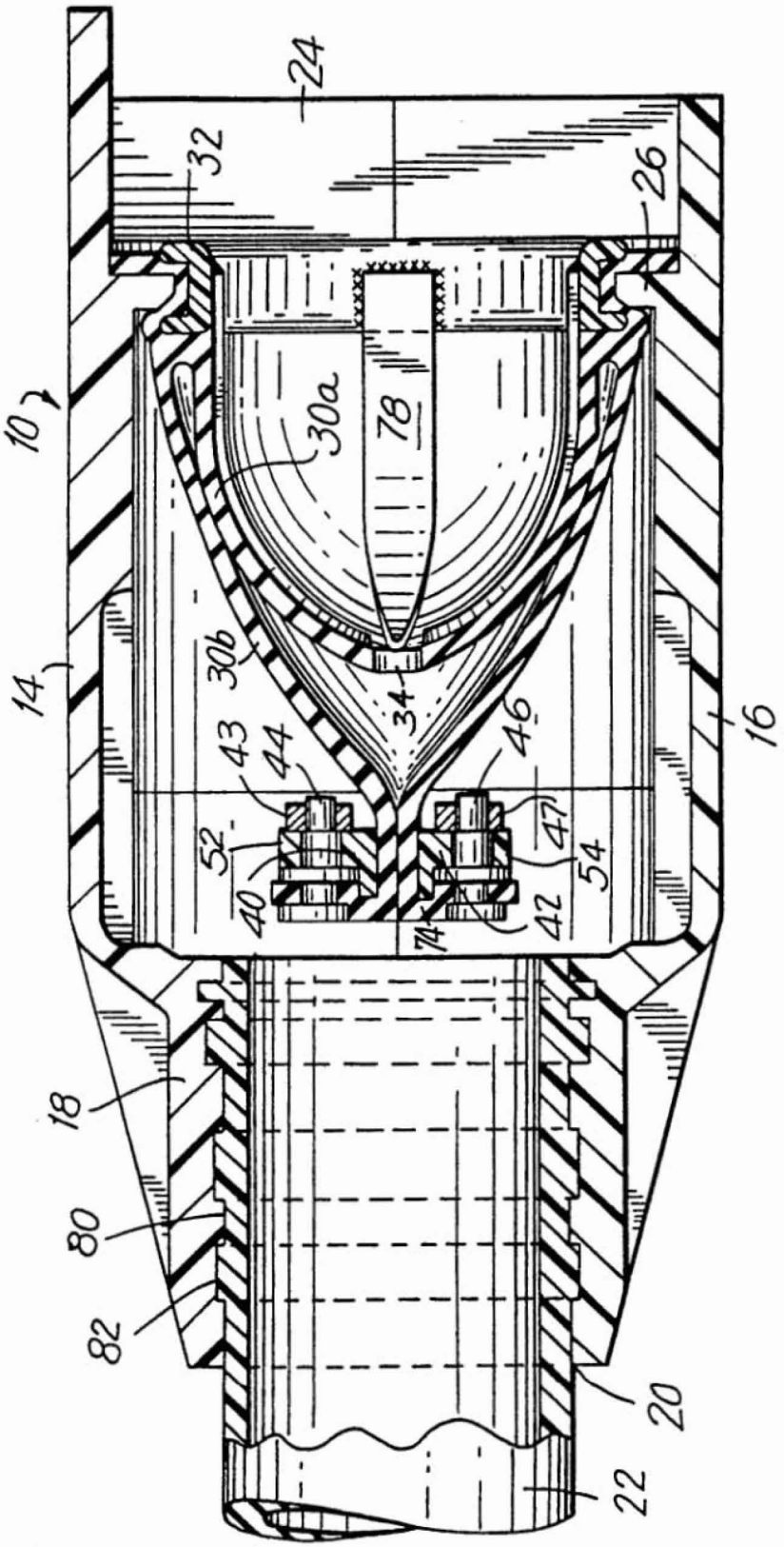
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FIG. 4

VALVE SYSTEM FOR INTRODUCING OBJECTS INTO ANATOMICAL BODY PORTIONS

This is a continuation of copending application Ser. No. 07/711,756 filed Jun. 7, 1991 now U.S. Pat. No. 5,120,373.

BACKGROUND OF THE INVENTION

1. Field Of The Invention

This invention relates to valve systems of the type adapted to allow the introduction of a surgical instrument into a patient's body. In particular, the invention is applicable to a cannula assembly and the like wherein a cannula extends from a valve assembly and is intended for insertion into a patient's body and an instrument is inserted into the patient's body through the cannula.

2. Background Of The Prior Art

In laparoscopic procedures surgery is performed in the interior of the abdomen through a small incision; in endoscopic procedures surgery is performed in any hollow viscus of the body through narrow endoscopic tubes or cannula inserted through a small entrance incision in the skin. Laparoscopic and endoscopic procedures generally require that any instrumentation inserted into the body be sealed, i.e. provisions must be made to ensure that gases do not enter or exit the body through the laparoscopic or endoscopic incision as, for example, in surgical procedures in which the surgical region is insufflated. Moreover, laparoscopic and endoscopic procedures often require the surgeon to act on organs, tissues, and vessels far removed from the incision, thereby requiring that any instruments used in such procedures be relatively long and narrow.

For such procedures, the introduction of a tube into certain anatomical cavities such as the abdominal cavity is usually accomplished by use of a system comprised of a cannula assembly and a trocar. A cannula assembly is formed of a cannula attached to a valve assembly which is adapted to maintain a seal across the opening of the valve assembly. Since the cannula is in direct communication with the internal portion of the valve assembly, insertion of the cannula into an opening in the patient's body so as to reach the inner abdominal cavity should be adapted to maintain a fluid tight interface between the abdominal cavity and the outside atmosphere.

Since surgical procedures in the abdominal cavity of the body require insufflating gases to raise the cavity wall away from vital organs, the procedure is usually initiated by use of a Verres needle through which a gas is introduced into the body cavity. Thereafter, a trocar, which is a sharp pointed instrument, is inserted into a cannula assembly and used to puncture the peritoneum, i.e. the inner lining of the abdominal cavity wall. The gas provides a slight pressure which raises the wall surface of the peritoneum away from the vital organs thereby avoiding unnecessary contact with the organs by the instruments inserted into the cannula. This procedure also provides the surgeon with an adequate region in which to operate. Laparoscopic or endoscopic surgical instruments may then be inserted through the cannula to perform surgery within the abdominal cavity or other body portion. The cannula is also utilized for introducing tubes into the body as for drainage purposes or the like.

In view of the need to maintain the atmospheric integrity of the inner area of the cavity, a valve assembly which permits introduction of a trocar or any surgical instrument and which permits selective communication of the inner atmosphere of the cavity with the outside atmosphere is desirable. In this regard, there have been a number of attempts in the prior art to provide such atmospheric integrity.

One form of cannula assembly includes a valve assembly which includes a flapper valve which is pivotally mounted within the valve assembly and is automatically opened by the trocar or other object when it is inserted into the proximal end of the valve assembly. See, e.g., U.S. Pat. No. 4,943,280 to Lander.

U.S. Pat. No. 4,960,412 relates to a catheter introducing system which includes a valve assembly having dual flexible resilient gaskets which permit introduction of a catheter by providing dual openings which are dimensioned to contact a catheter tube introduced into the unit. Introduction of the tube is accomplished by introducing the tube into the openings of the gaskets. A first valve prevents or minimizes the flow of blood from the valve assembly unit when the catheter tube is absent and the second valve prevents or minimizes the flow of blood from the valve assembly when the catheter tube is present.

Another valve includes finger operated levers for controlling an inner valve formed of a plurality of radially movable members which join in adjacent relation to close the valve opening and which separate to permit entry of an element into the valve opening. The members are concentrically positioned and arranged to block the opening when the levers are at rest and to open in a manner to form a substantially circular passage-way when the levers are squeezed toward each other against the bias of a spring positioned therebetween.

Although attempts have been somewhat successful in providing a valve assembly which maintains the integrity of the atmospheric interface between the inlet of the valve assembly and the atmosphere outside the valve assembly, none have provided the degree of control to the user whereby opening adapted to facilitate the introduction of an instrument into the human body can be controlled selectively, opened or closed, in sequence and in a manner which positively retains the desired interface between the two atmospheres as may be required by the operator. The present invention provides a valve assembly which may be incorporated into a cannula assembly or utilized in combination with any type of tubular member for introduction into the body of a patient while permitting introduction of instruments into the body. At all times, the surgeon maintains control over the interface between the atmospheres within and without the patient's body. Moreover, the present invention makes it possible to introduce instruments of varying sizes into the body and insures the maintenance of a gas seal despite instrument manipulation therethrough.

SUMMARY OF THE INVENTION

A valve assembly adapted for introduction of an elongated object into a patient's body is provided which comprises first valve means formed of a resilient material and defining an aperture for reception of the object, the aperture being configured and dimensioned such that insertion of the object into the aperture will cause the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner. Second valve means is positioned adjacent the first valve means in general alignment

therewith, the second valve means defining an aperture in general alignment with the aperture of the first valve means and being formed of a flexible material at least in the region defining the aperture. Means is provided to selectively permit the aperture of the second valve means to be opened or closed so as to permit entry of the object.

Preferably, the valve assembly comprises valve body means which defines proximal inlet and distal outlet openings. The first valve means is formed of an elastomeric resilient material and extends across the proximal inlet opening of the valve body, and defines an aperture configured and dimensioned for reception of the object in a manner such that resilient material surrounding the aperture engages the surface of the object to provide a substantially fluid tight seal which prevents passage of fluids past the interface. The second valve means is positioned adjacent and distally of the first valve means and both valve means extend across the proximal inlet opening of the valve body. The second valve means includes an aperture defined at least in part by flexible elastomeric material in general alignment with the aperture of the first valve means and of dimension sufficient to permit passage of the object after the object is passed through the first valve means. Means is provided to bias the flexible material defining the aperture of the second valve means to a configuration whereby the aperture is closed to form a fluid tight seal prior to inserting the object therethrough, and means is provided to open the aperture of the second valve means to permit passage of the object therethrough after the object is passed through the first valve means. Preferably, means to open the aperture of the second valve means is manually operable.

The objects contemplated are surgical instruments such as clip appliers, dissectors, graspers, laser and electrocautery devices, drainage or fluid introduction tubes or the like. The first valve means is positioned across the proximal opening of the valve body and the second valve means is positioned adjacent the first valve means and distally thereof. Further, the first and second valve means are preferably formed integrally of a flexible elastomeric resilient material, with the first valve means connected to the second valve means at the proximal ends thereof, the first valve means being positioned at least partially within the second valve means. The first and second valve means are joined at their proximal ends and are attached to the valve body across the proximal opening. The valve body includes a neck which extends distally of the distal end thereof, the neck defining an opening communicating with the interior of the valve body means. Further, the distally extending neck of the valve body is adapted to receive a tubular cannula such that the cannula extends distally of the valve body.

The second valve means comprises an elastomeric generally cylindrically shaped member which is preferably connected integrally at the proximal end thereof to the proximal end of the first valve means and is open at the distal end. The distal opening of the second valve means is capable of being closed by collapsing the distal end until the half portions thereof resiliently contact each other to form a substantial fluid tight seal. The distal end of the second valve means is biased toward the closed fluid tight position by a clamp which is positioned and adapted to bias the open end of the second valve means toward the collapsed configuration. The clamp comprises a pair of clamp blades, each blade connected to a portion of the distal open end of the second valve means. The clamp blades are each biased toward each other to close the distal opening of the second valve means by a respective torsion spring mounted within the valve body. Each clamp blade is connected to a pivotal arm and each pivotal arm is biased toward the position corresponding to the closed position of the second valve means. The pivotal arms are mounted for pivotal movement toward the valve-open position by reception into an aperture of at least one slidable pin. The pins are movable manually by engagement by the user's fingers.

The first and second valve means are preferably attached to and supported by an annular ring which includes a plurality of elongated fingers which extend distally therefrom and are positioned within the first valve means in contact with the inner surface thereof. The fingers provide an interface between the first valve means and objects inserted therein and assist in spreading the opening of the first valve means for entry of the instrument. Further, the fingers distribute the force over the inner surface of the first valve means.

Each slidable pin has a frusto-conical shaped tip adjacent each pivot arm for engagement with the respective pivot arm when the pins are moved toward each other by manual action of the user. Further, the valve body is preferably a two piece valve housing assembled at a medial interface and constructed of a relatively rigid plastic material such as polycarbonate, polyethylene or the like.

In a preferred embodiment, a cannula and trocar assembly is provided for puncturing a body wall of a patient for the introduction of elongated objects as surgical instruments or the like into the body of the patient while maintaining a substantial fluid tight seal between internal body portions and the outside atmosphere at all times prior to and after insertion of the object. The valve housing has an inlet opening at the proximal end and an outlet opening at the distal end, the distal end opening having a tubular cannula extending distally therefrom. A trocar is positioned within the valve housing and the cannula for puncturing the body wall. Thereafter, the trocar is removed and elongated objects such as surgical instruments or the like may be introduced into the patient's body through the valve assembly and cannula as described hereinabove.

In the preferred embodiment the first and second valves are molded integrally of synthetic or natural rubber and are connected at a common proximal end which defines the proximal opening. The first valve means has a generally conical shape and is positioned within the second valve means in a generally concentric fashion. The valve means are mounted onto a support ring which is used to mount the valve means to an annular portion within the valve housing.

A method is provided for selectively sealing a valve assembly for communication with inner portions of a patient's body while permitting introduction of an elongated instrument therethrough, the valve assembly having a proximal inlet opening and a distal outlet opening, comprising providing first valve means comprised of resilient material defining an opening which permits entry therethrough by the instrument while resiliently contacting the outer surface, providing second valve means distal of the first valve means, and selectively controlling the open and closed condition of the second valve means to permit passage of the instrument after entry through the first valve means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded perspective view of a cannula assembly illustrating the valve assembly constructed according to the present invention;

FIG. **2** is a view of the lower housing half section shown in FIG. **1** with portions of the inner valve and cannula cut away for illustration purposes;

FIG. **3** is a cross-sectional view of the valve assembly of the present invention taken along lines **3—3** of FIG. **2**; and

FIG. **4** is a cross-sectional view of the valve assembly of the present invention, taken along lines **4—4** of FIG. **2**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention contemplates introduction into a patient's body of all types of surgical instruments including clip appliers, lasers, photographic devices, tubes, etc. All such objects are referred to herein as "instruments".

Referring initially to FIGS. **1** and **2**, a cannula assembly **10** is illustrated having the novel valve assembly **12** constructed according to the present invention. Valve assembly **12** includes a valve housing **15** formed of upper housing half section **14** and lower housing half section **16** shown separated in FIG. **1** for convenience of illustration.

The housing half sections **14,16** are formed of a suitable desirable plastic material such as polycarbonate, polyethylene or the like. One preferred material is LEXAN brand polycarbonate manufactured and marketed by General Electric Company, Pittsfield, Mass. The housing half sections **14,16** are normally attached along the seam by suitable attachment techniques such as adhesive, ultrasonic welding, or the like.

The valve housing **15** includes neck **18** at the distal end having an aperture **20** dimensioned for reception of an appropriate sheath tube such as cannula **22** to form the cannula assembly **10**. The proximal end of valve housing **15** includes inlet opening **24** which includes annular partition **26** for supporting a dual diaphragm as will be described.

Referring now to FIG. **2**, the lower housing half section **16** is shown with the upper housing half section **14** removed, so as to illustrate the novel inner valve mechanism of the present invention. The valve mechanism is shown partially cut away and in cross section. Dual flexible elastomeric sealing diaphragm **30** extends across the aperture **20** of housing **15** as shown. The diaphragm **30** forms a circular rib **33** which fits tightly by snap fit onto annular partition **26** with dual flanged circular rib **32** as shown in FIG. **2**. The annular partition **26** is constructed of the same relatively rigid plastic material such as polycarbonate, polyethylene or the like, as the valve housing, while diaphragm **30** is constructed of an elastomeric material such as synthetic or natural rubber. Diaphragm **30** is of dual walled construction as shown, with the inner wall **30***a* having a central aperture **34** for reception of an instrument as will be described.

Referring now to FIG. **1** in conjunction with FIGS. **3** and **4**, outer wall **30***b* has formed at the distal end, a pair of ears **36,38** which are connected to clamp blades **40,42** as shown, by suitable pivot pins **44,46** and attachment nuts **43,47**. Each clamp blade **40,42** is biased in a direction toward the other by a torsion spring **48,50** having one leg in engagement with the adjacent housing wall and the other leg in engagement with pivotal arm **52,54** respectively pivotally mounted at pivot pin **56,58** as shown in FIG. **3**. Each pivot arm **52,54** extends as shown, into the path of a pin **60,62** which is slidably mounted within elongated opening **64,65** having a circular cross-section similar to the cross-section of the pins **60,62**. The inner end of each pin has an opening **66,68** for reception of the appropriate pivotal arm **52,54** such that manually depressing the slidable pins **60,62** toward each other by engagement of transverse buttons **70,72** with the thumb and index finger causes pivotal arms **52,54** to pivotally rotate arms **52,54** away from each other. This motion causes clamp blades **40,42** with ears **36,38** to separate causing outer wall **30***b* of dual diaphragm **30** to open at the distal end to the configuration shown in FIG. **1**. When the pins **60,62** are released, the outer wall **30***b* of diaphragm **30** collapses to the configuration shown in FIGS. **3** and **4** under action of clamp blades **44,46** and springs **48,50**, thus causing outer wall to collapse to the duckbill shape **74**, providing a fluid tight seal between the proximal end of the diaphragm **30** and the distal end.

Referring now to FIG. **4** in conjunction with FIG. **1**, inner elastomeric wall **30***a* of diaphragm **30** defines circular central aperture **34** at the distal end which is dimensioned less than or equal to the outer diameter of any instrument intended for entry into the proximal end of the valve assembly. Preferably, diaphragm **30** is fabricated from a material which is sufficiently resilient to accommodate and provide a fluid seal with instruments of varying diameters, e.g., diameters of from 5 mm to 10 mm. In FIG. **1** an endoscopic clip applying apparatus is shown at **76**. However, any elongated relatively narrow instrument is contemplated.

Referring once again to FIG. **3** in conjunction with FIG. **1**, diaphragm mounting and stabilizing device **31** is formed of dual flanged circular ribbed ring **32** having distally extending fingers **78** tapered at their free ends as shown. Diaphragm **30** is mounted to dual flanged circular ring **32** as shown in FIG. **4** and the entire assembly is mounted to annular partition **26** as shown. Fingers **78** are positioned within diaphragm inner wall **30***a* and are sufficiently flexible to conform to the shape of the inner wall while providing some degree of stability to the inner wall. Fingers **78** also assist in spreading inner wall **30***a* to expand aperture **34** when an instrument is inserted by distributing the spreading force more evenly. In addition to facilitating expansion of aperture **34** to conform to instrument **76**, fingers **78** minimize the risk of damage to elastomeric inner wall **30***a*, e.g., puncture thereof, by providing an interface between the instrument **76** and the inner wall. Stabilizing device **31** is fabricated of a suitable flexible plastic material such as polyester, polypropylene, etc. and fingers **78** are preferably formed integral with dual flanged ring **32**. Further, fingers **78** are sufficiently thin and flexible such that insertion into inner wall **30***a* of diaphragm **30** causes them to assume an initial arcuate shape as shown in FIGS. **2** and **4**, similar to the generally conical shape of inner wall **30***a*.

Upon insertion of instrument **76** into housing opening **20** and through aperture **34** of inner wall **30***a*, the elastomeric material of wall **30***a* will expand or stretch around the instrument **76** to form a fluid tight seal. The seal is of sufficient fluid tight character that media such as pressurized gases used to insufflate a body cavity or body liquids will not pass the interface between diaphragm

inner wall **30***a* and the instrument **76**. Aperture **34**, in its non-expanded or non-stretched condition, is typically approximately 3 to 15 mm to accommodate elongated endoscopic instruments while maintaining sufficient sealed contact with the other surface thereof. However, such dimensions will vary depending upon the size of the instruments and the intended application. Further, manipulation of the instrument in any direction will not affect the seal, since the elastomeric material will remain in tight contact with the outer surface of the instrument.

At the point when the instrument **76** has passed the inner wall **30***a* and entered aperture **34**, a gas tight seal has been created between the instrument and the inner wall **30***a*. The surgeon then squeezes pins **60,62** with the thumb and index finger causing the distal end of outer wall **30***b* of diaphragm **30** to expand to the shape shown in FIG. **1** thus permitting continued entry of the instrument **76** through the entire valve body housing **15** and into the cannula **22**. Depending upon the particular procedure, the surgeon may prefer to squeeze pins **60,62** thereby opening outer wall **30***b* prior to entry of instrument **76** into the valve housing **15** and into diaphragm inner wall **30***a*.

Cannula **22** is connected to the distal end of the valve housing at neck **18** which has a series of alternating circular shaped ribs **80** and valleys **82**. Cannula **22** is fabricated of a rigid material such as a plastic, fiberglass or metal and is supported in position as shown in FIGS. **2** and **4** within neck **18** by the ribs **80** which are formed of the same material. Alternatively, the tube **22** may be of elastomeric material in which case it would simply be flexible and resilient so as to be assembled with distal neck **18** by inserting the tube into the neck and distorting the outer shape until it is snapped into position as shown within ribs **80**.

The operation of the valve assembly will now be described. The valve assembly is intended to be supplied as part of a cannula assembly, i.e. a valve assembly with distal cannula tube **22** positioned as shown. A trocar is a sharp pointed instrument usually fitted within a cannula assembly and used to insert the cannula into a body cavity by first piercing an aperture in the cavity wall (i.e., the peritoneum). The cannula is then inserted into the punctured body wall of the patient. Thereafter, the trocar is removed, permitting insertion of instruments into the patient's body through the cannula to perform the desired procedure. Thus, the significance of providing control to the surgeon of the sealed state of the opening in the cannula assembly cannot be overemphasized. Such opening will ultimately control the exposure between the internal part of the body cavity and the outside atmosphere. For laparoscopic procedures the valve assembly will preserve the state of insufflation of the peritoneum during the surgical procedures.

The surgeon removes the trocar from the cannula assembly thereby permitting the opening of outer wall **30***b* of diaphragm **30** to close automatically under the action of springs **48,50**. Thereafter, the surgeon inserts an instrument into the body cavity by first inserting it into the proximal end of the valve assembly, through dual flanged ring **32** and then through aperture **34** of inner diaphragm wall **30***a*. Pins **60,62** may be selectively squeezed as desired by the surgeon to open the distal end of outer wall **30***b* to permit entry of the instrument into cannula **22** and into the body cavity. At this point, the tight contact between the instrument **76** and the diaphragm inner wall **30***a* at aperture **34** has sealed the inner body cavity from the outside atmosphere. This seal is provided by the resilient property of the stretched elastomeric material surrounding opening **34**. Thus, separating clamp plates **40,42** to open outer diaphragm wall **30***b* to permit entry of instrument **76** into cannula **22** does not affect the sealed condition of the inner anatomical cavity. As noted previously, manipulation of the instrument in any direction will not affect the seal, since the elastomeric material defining the opening **34** will conform to the movements of the instrument and assume an elliptical or other shape necessary to maintain contact.

As noted, aperture **34** is preferably dimensioned between 3 and 15 mm to accommodate laparoscopic and endoscopic instruments such as clip appliers, laser tubes, photographic instruments, tubes or the like. However, depending upon need or application this dimensional range may be varied to accommodate any particular instrument.

The opening at the distal end of outer wall **30***b* is always under the surgeon's control through pins **60,62** and is adapted to be automatically actuated to the closed duckbill shaped position **74** under action of springs **48,50** when the surgeon removes the instrument **76** or other object from the valve assembly. Further, manipulation of the instrument **76** does not affect the shape of aperture **34** or the sealing contact of inner wall **30** or with the instruments because diaphragm **30** is sufficiently flexible and resilient to maintain contact with the surface of the instrument **76**. Thus, during the entire sequence the integrity of the seal between the inside of the body cavity and the outside atmosphere is clearly maintained at all times.

We claim:

1. Valve assembly for sealed reception of an elongated object, which comprises:

a) valve body defining a longitudinal axis and having at least one opening configured and dimensioned to permit entry of the elongated object;

b) flexible resilient valve member defining an aperture positioned in general alignment with said at least one opening; and

c) means associated with said flexible resilient valve member to facilitate expansion of said aperture to permit entry of the elongated object therethrough in sealed engagement therewith, said means to facilitate expansion of said aperture adapted for radial displacement relative to said longitudinal axis and positioned to expand said aperture upon contact with the elongated object as the elongated object is at least partially inserted into said at least one opening of said valve body.

2. Valve assembly according to claim **1** wherein said resilient valve member is adapted to engage and conform to the outer surface of the elongated object in substantially fluid tight manner.

3. Valve assembly for sealed reception of an elongated object, which comprises:

a) valve body having means configured and dimensioned to permit entry of the elongated object;

b) flexible resilient valve means defining an aperture positioned in general alignment with said entry means; and

c) relatively rigid means associated with said resilient valve means and having portions adapted to be displaced relative to a central axis defined by said valve body upon contact with the elongated object

as the elongated object is at least partially inserted into said entry means of said valve body, said portions positioned and dimensioned to expand said aperture to permit entry of the elongated object therethrough during displacement of said portions.

4. Valve assembly according to claim **3** further comprising secondary valve means positioned adjacent said flexible resilient valve means and in general alignment therewith, said secondary valve means movable between a first position which blocks entry of the elongated object and a second position which permits entry of the elongated object.

5. Valve assembly according to claim **4** wherein said secondary valve means comprises at least one member movable toward and away with respect to a rigid member to respectively assume said first and second positions.

6. Valve assembly according to claim **5** comprising resilient means to bias said at least one member toward said rigid member.

7. Valve assembly according to claim **6** wherein said at least one member is adapted to provide a substantially fluid tight seal when in said first position.

8. Valve assembly according to claim **7** wherein said at least one member is pivotal between said first and second positions.

9. Valve assembly according to claim **5** wherein said valve body is a rigid housing.

10. Valve assembly according to claim **9** wherein said valve body is a trocar housing.

11. Valve assembly according to claim **10** wherein the elongated object is a trocar.

12. Valve assembly for introduction of an elongated object into a patient's body, which comprises:

a) valve body member defining a proximal inlet opening and a distal outlet opening;

b) first valve member formed of a flexible elastomeric resilient material and defining an aperture for reception of the elongated object, said aperture being configured and dimensioned such that insertion of the elongated object into said aperture causes said flexible resilient material defining said aperture to resiliently engage and conform to an outer surface portion of the elongated object in substantially fluid tight manner;

c) second valve member positioned adjacent said first valve member and in general alignment therewith, said second valve member defining an aperture in general alignment with said aperture of said first valve member, and being formed of a flexible resilient material at least in the region adjacent to and defining said aperture; and

d) means engageable with the elongated object upon insertion thereof into said proximal inlet opening of said valve body member, and adapted to be radially displaced relative to a central axis defined by said valve body member to facilitate expansion of said aperture of said first valve member to facilitate entry of the object therein.

13. The valve assembly according to claim **12** wherein said first and second valve members are formed integral of a flexible elastomeric resilient material, said first valve member connected to said second valve member at the proximal end thereof, said first valve member being positioned at least partially within said second valve member.

14. Valve assembly according to claim **13** wherein said proximal end of said first and second valve members is attached to and supported by an annular ring.

15. Valve assembly according to claim **14** wherein said means engageable with the elongated object comprises a plurality of elongated resilient fingers associated with said valve body, said resilient fingers positioned within said first valve member in supporting contact with inner surface portions thereof and engageable with the elongated object upon at least partial insertion of the elongated object into said proximal inlet opening of said valve body member, said fingers adapted for radial displacement relative to a longitudinal axis defined by said annular ring upon engagement with the elongated object to radially expand said aperture of said first valve member to facilitate entry of the elongated object.

16. Valve assembly according to claim **15** wherein said annular ring member comprises a flexible plastic material selected from the group consisting of polyester and polypropylene and said plurality of elongated resilient fingers associated with said valve body are integral with said annular ring.

17. Valve assembly according to claim **16** wherein said means engageable with the elongated object comprises four of said flexible fingers.

18. Valve assembly according to claim **12** further comprising manually operable means for selectively opening said aperture of said second valve member whereby the object may pass therethrough.

19. Valve assembly adapted for introduction of an elongated object into a patient's body, which comprises:

a) first valve means formed of a resilient material and defining an aperture for reception of the elongated object, said aperture being configured and dimensioned such that insertion of the elongated object into said aperture will cause the resilient material defining said aperture to resiliently engage the outer surface of the elongated object in substantially fluid tight manner;

b) second valve means positioned adjacent said first valve means in general alignment therewith, said second valve means defining an aperture in general alignment with said aperture of said first valve means, and being formed of a flexible material at least in the region defining said aperture;

c) means associated with said first valve means and engageable with the elongated object as the elongated object is at least partially inserted into said aperture of said first valve means, and adapted to be radially displaced to facilitate expansion of said aperture of said first valve means during introduction of the elongated object within the valve assembly; and

d) manually operable means to selectively permit said aperture of said second valve means to be opened or closed so as to permit entry of the elongated object.

20. Valve assembly adapted for introduction of an elongated object into a patient's body, which comprises:

a) first valve means formed of a resilient material and defining an aperture for reception of the elongated object, said aperture being configured and dimensioned such that insertion of the elongated object into said aperture will cause the resilient material defining said aperture to resiliently engage the outer surface of the elongated object in substantially fluid tight manner;

b) second valve means positioned adjacent said first valve means in general alignment therewith, said second valve means defining an aperture in general alignment with said aperture of said first valve means, and being formed of a flexible material at least in the region defining said aperture;

c) a plurality of distally extending resilient flexible fingers formed integral with a valve support ring and positioned within said first valve means in supporting contact with inner surface portions thereof, said fingers configured and dimensioned to engage the elongated object during introduction of the elongated object within the valve assembly, whereby engagement of the elongated object by said resilient fingers causes radial displacement of said fingers relative to a longitudinal axis defined by said support ring so as to cause radial expansion of said aperture of said first valve means to facilitate entry of the elongated object.

21. Valve assembly for sealed reception of an elongated object, which comprises:

a) valve body defining at least one opening configured and dimensioned to permit entry of the elongated object;

b) flexible resilient valve member defining an aperture positioned in general alignment with said at least one opening in said valve body; and

c) at least two relatively rigid members associated with said valve member and engageable with the elongated object upon introduction into said at least one opening of said valve body, and adapted to be radially displaced relative to a central axis of said valve body to facilitate expansion of said aperture of said resilient valve member prior to entry of the elongated object into said aperture.

22. Valve assembly for sealed reception of an elongated object into a patient's body, which comprises:

a) valve body defining a first inlet opening and a second outlet opening;

b) flexible resilient valve member defining an aperture positioned in general alignment with at least said first inlet opening for reception of the elongated object, said aperture being configured and dimensioned such that insertion of the elongated object into said aperture will cause the flexible resilient material defining said aperture to resiliently engage and conform to the outer surface of the elongated object in a substantially fluid tight manner; and

c) means engageable with the elongated object upon insertion thereof into said first inlet opening and adapted to be displaced away from a central axis defined by said valve body to expand said aperture of said resilient valve member to facilitate entry of the elongated object therein.

23. Valve assembly according to claim **22** wherein said means engageable with the elongated object comprises valve support means, said valve support means being adapted to support said resilient valve member and including a support ring having at least two distally extending resilient flexible fingers positioned within said resilient valve member in supporting contact with the inner surface thereof, whereby engagement of the elongated object by said at least two resilient fingers causes radial displacement of said fingers relative to a longitudinal axis defined by said support ring so as to cause radial expansion of said aperture of said resilient valve member to facilitate entry of the elongated object.

24. Valve assembly according to claim **23** wherein each said flexible finger has a proximal end portion and a distal end portion, each said distal end portion of said flexible fingers being disposed radially inwardly of said corresponding proximal end portion.

25. Valve assembly according to claim **24** wherein said distal end portions of said flexible fingers are each generally angularly displaced relative to said longitudinal axis defined by said support ring.

26. Valve assembly for sealed reception of an elongated object, which comprises:

a) valve body defining a generally longitudinal axis and having at least one opening configured and dimensioned to permit entry of the object;

flexible resilient valve member positioned within said valve body and defining an aperture positioned in general alignment with said at least one opening of said valve body; and

c) at least two projecting members associated with said flexible resilient valve member and extending in a generally distal direction, each said at least two projecting members having at least a portion thereof adapted to move generally radially to facilitate expansion of said aperture to permit entry of the elongated object therethrough in sealed engagement therewith.

27. Valve assembly according to claim **26** wherein each said projecting member has a proximal end portion and a distal end portion which is disposed generally radially inward of said corresponding proximal end portion.

28. Valve assembly according to claim **27** wherein portions of said at least two projecting members adapted to move radially to facilitate said expansion of said aperture are located at the distal end portions of said projecting members.

29. Valve assembly according to claim **28** wherein each said distal end portion of said projecting members is generally oriented at an angle relative to said longitudinal axis.

30. Valve assembly according to claim **29** wherein said at least two projecting members contact at least a portion of said resilient valve member and are positioned for engagement with the elongated object upon insertion thereof into said at least one opening of said valve body, at least portions of said at least two projecting members adapted for generally radial displacement relative to said longitudinal axis upon engagement by the elongated object to cause radial expansion of said aperture.

31. Valve assembly according to claim **30** wherein said projecting members are attached to an annular ring.

32. Valve assembly according to claim **31** wherein said annular ring comprises a material selected from the group consisting of polyester and polypropylene, said projecting members being integrally formed with said annular ring.

33. Valve assembly according to claim **32** wherein said projecting members are monolithically formed with said annular ring.

34. Valve assembly according to claim **33** wherein at least four of said projecting members are provided.

35. Valve assembly for sealed reception of an elongated object, which comprises:

a) valve body defining an inlet opening configured and dimensioned to permit entry of the elongated object;

b) flexible resilient valve member defining an aperture positioned in general alignment with said inlet opening; and

c) at least one relatively rigid member having at least a portion thereof adapted to be displaced radially relative to a central axis defined by said valve body, said at least a portion of said at least one relatively rigid member positioned and dimensioned to expand said aperture of said flexible resilient valve member upon contact with the elongated object as the elongated object is at least partially inserted into said inlet opening.

36. Valve assembly according to claim **35** comprising at least two said relatively rigid members.

37. Valve assembly according to claim **35** comprising at least four said relatively rigid members.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,304,143
DATED : April 19, 1994
INVENTOR(S) : David T. Green, et al

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, Item [75] Inventor: should read --David T. Green, Westport; Henry Bolanos, East Norwalk; Henry Sienkiewicz; all of Connecticut--

Signed and Sealed this

Second Day of August, 1994

Attest:

Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks

US005685854A

United States Patent [19]

Green et al.

[11] Patent Number: 5,685,854

[45] Date of Patent: Nov. 11, 1997

[54] **VALVE SYSTEM FOR INTRODUCING OBJECTS INTO ANATOMICAL BODY PORTIONS**

[75] Inventors: **David T. Green**, Westport; **Henry Bolanos**, East Norwalk; **Henry Sienkiewicz**, Stamford, all of Conn.

[73] Assignee: **United States Surgical Corporation**, Norwalk, Conn.

[21] Appl. No.: **185,102**

[22] Filed: **Jan. 21, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 992,143, Dec. 17, 1992, Pat. No. 5,304,143, which is a continuation of Ser. No. 711,756, Jun. 7, 1991, Pat. No. 5,180,373.

[51] **Int. Cl.**[6] **A61M 39/22**

[52] **U.S. Cl.** **604/167**; 604/256

[58] **Field of Search** 604/167, 256

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Primary Examiner—Paul J. Hirsch

[57] **ABSTRACT**

A valve assembly adapted for introduction of an elongated object into a patient's body having a first valve formed of a resilient material and defining an aperture for reception of the object, the aperture being configured and dimensioned such that insertion of the object into the aperture will cause the resilient material defining the aperture to resiliently engage the outer surface of the object in a fluid tight manner. A second valve is positioned adjacent and distal of the first valve in general alignment therewith, whereby the second valve defines an aperture in general alignment with the aperture of the first valve, and is formed of a flexible material at least in the region defining the aperture. A pair of manually operable clamps are provided to selectively permit the aperture of the second valve to be opened or closed so as to permit entry of the object such that the object first passes through the first valve and then the second valve prior to entry into the patient's body.

10 Claims, 4 Drawing Sheets

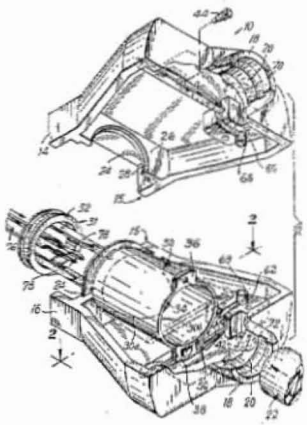

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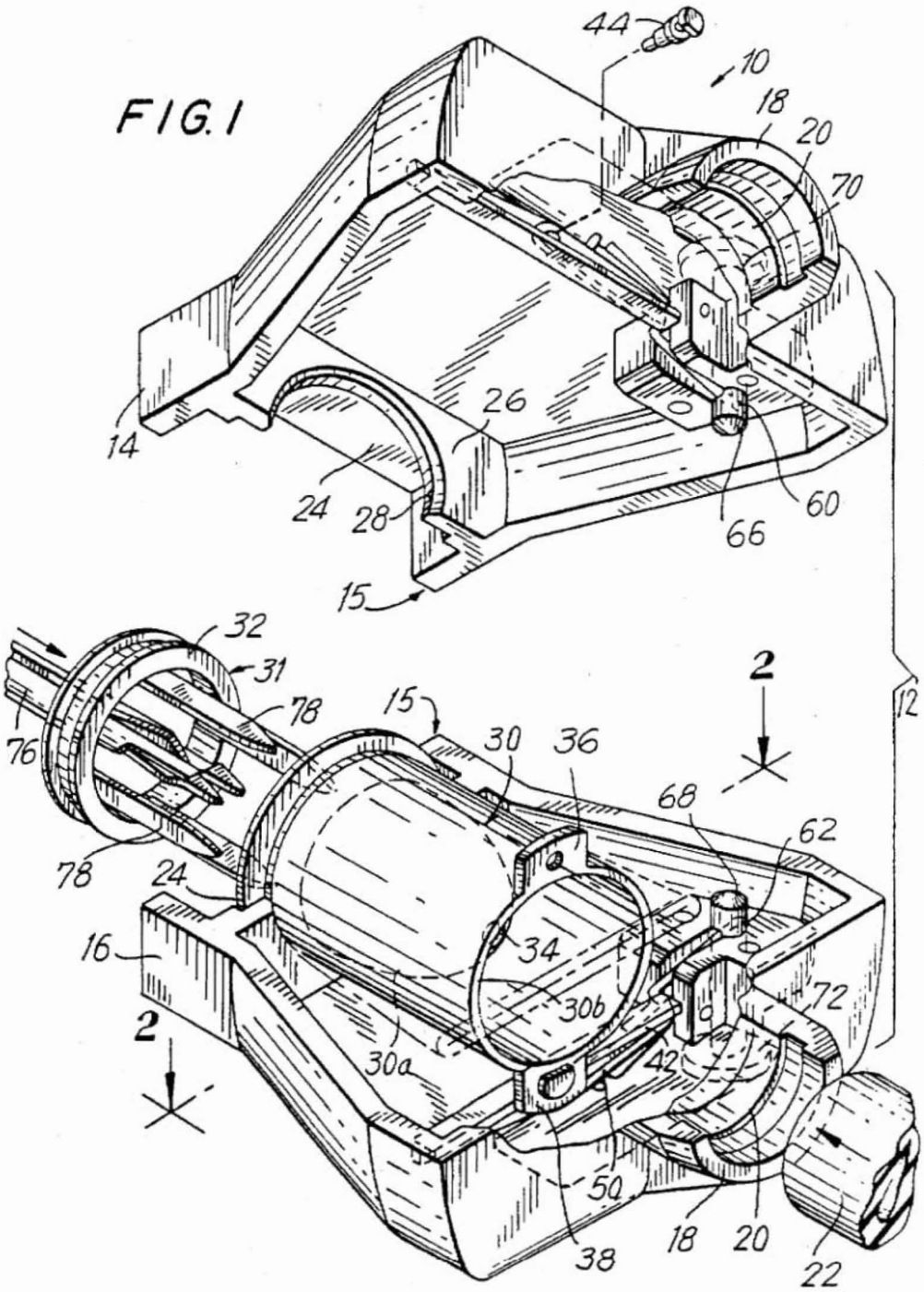
FIG. 1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30b
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2
30a
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18
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22
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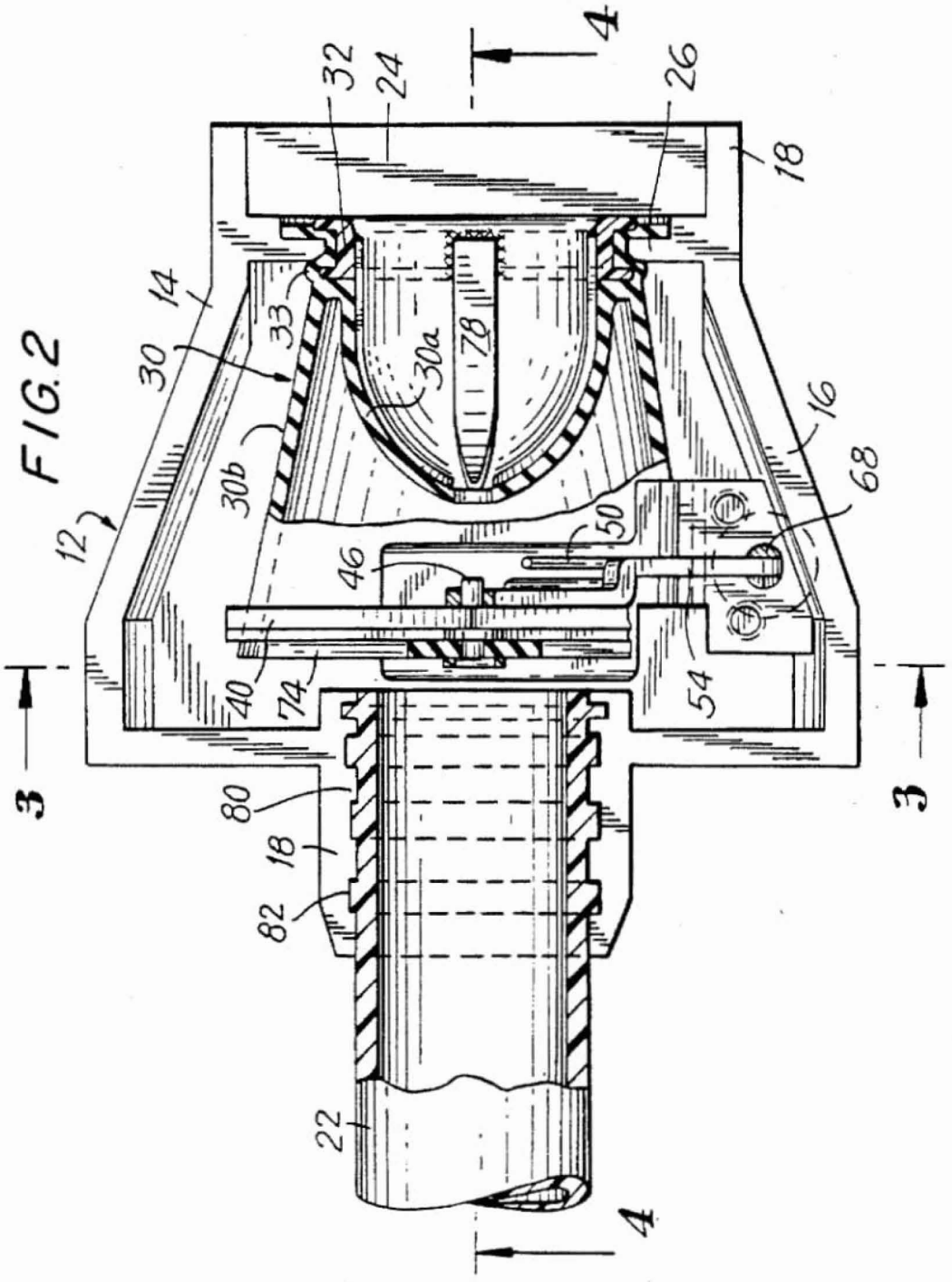
FIG. 2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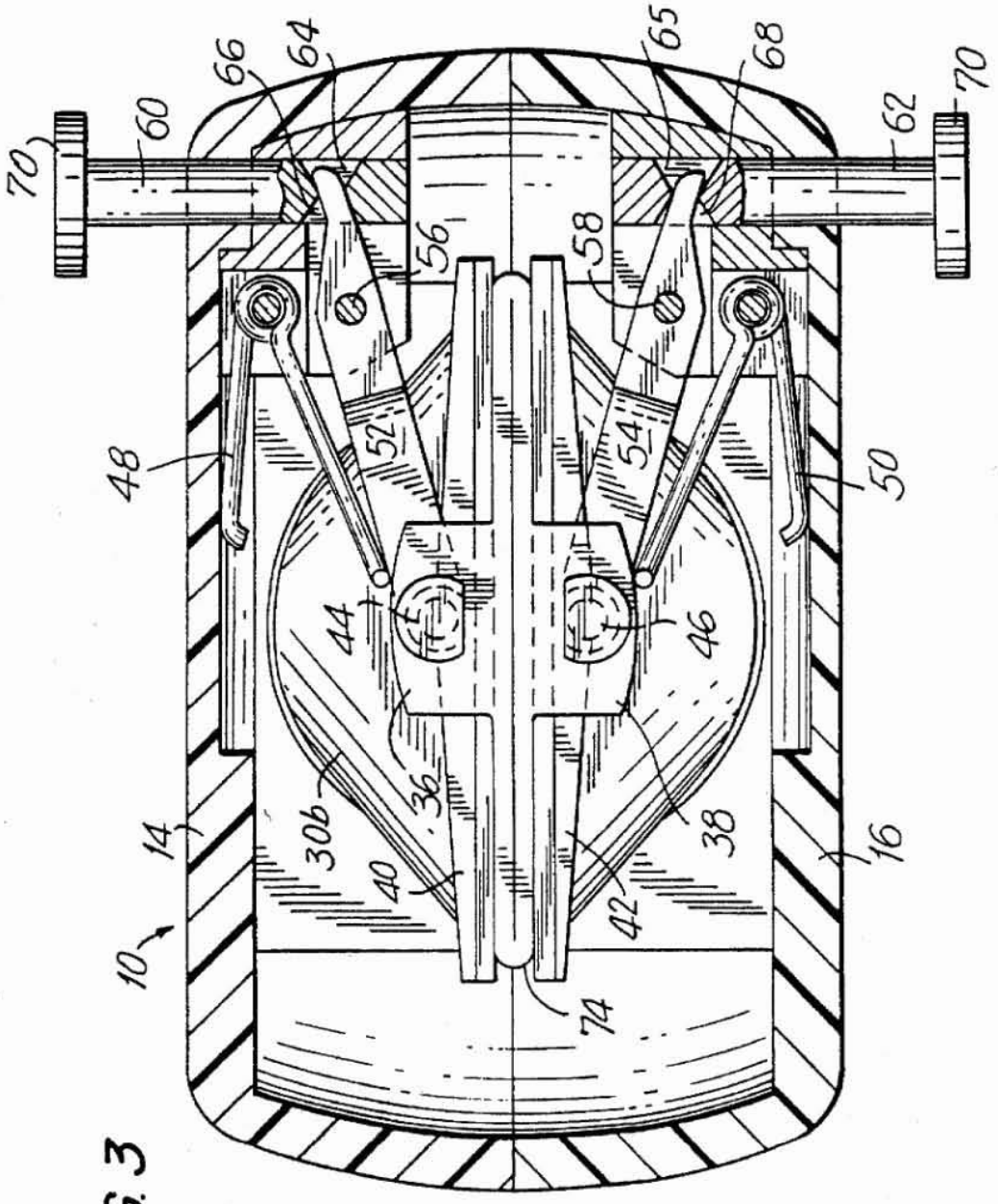
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30b
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FIG. 3

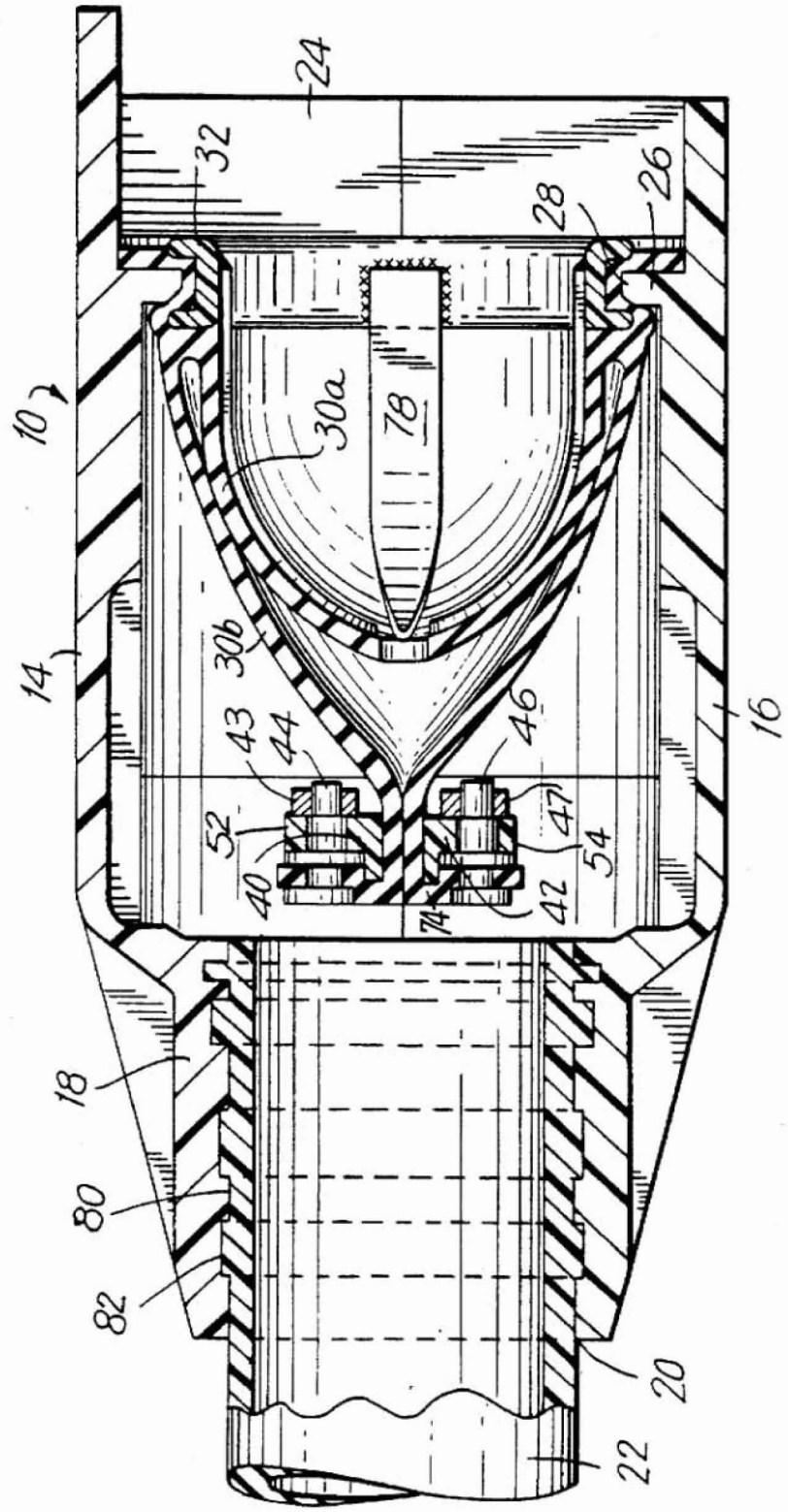
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FIG. 4

VALVE SYSTEM FOR INTRODUCING OBJECTS INTO ANATOMICAL BODY PORTIONS

This is a continuation of U.S. application Ser. No. 07/992,143 filed Dec. 17, 1992, now U.S. Pat. No. 5,304,163, which is a continuation of U.S. application Ser. No. 07/711,756, filed Jun. 7, 1991, now U.S. Pat. No. 5,180,373.

BACKGROUND OF THE INVENTION

1. Field Of The Invention

This invention relates to valve systems of the type adapted to allow the introduction of a surgical instrument into a patient's body. In particular, the invention is applicable to a cannula assembly and the like wherein a cannula extends from a valve assembly and is intended for insertion into a patient's body and an instrument is inserted into the patient's body through the cannula.

2. Background Of The Prior Art

In laparoscopic procedures surgery is performed in the interior of the abdomen through a small incision; in endoscopic procedures surgery is performed in any hollow viscus of the body through narrow endoscopic tubes or cannula inserted through a small entrance incision in the skin. Laparoscopic and endoscopic procedures generally require that any instrumentation inserted into the body be sealed, i.e. provisions must be made to ensure that gases do not enter or exit the body through the laparoscopic or endoscopic incision as, for example, in surgical procedures in which the surgical region is insufflated. Moreover, laparoscopic and endoscopic procedures often require the surgeon to act on organs, tissues, and vessels far removed from the incision, thereby requiring that any instruments used in such procedures be relatively long and narrow.

For such procedures, the introduction of a tube into certain anatomical cavities such as the abdominal cavity is usually accomplished by use of a system comprised of a cannula assembly and a trocar. A cannula assembly is formed of a cannula attached to a valve assembly which is adapted to maintain a seal across the opening of the valve assembly. Since the cannula is in direct communication with the internal portion of the valve assembly, insertion of the cannula into an opening in the patient's body so as to reach the inner abdominal cavity should be adapted to maintain a fluid tight interface between the abdominal cavity and the outside atmosphere.

Since surgical procedures in the abdominal cavity of the body require insufflating gases to raise the cavity wall away from vital organs, the procedure is usually initiated by use of a Verres needle through which a gas is introduced into the body cavity. Thereafter, a trocar, which is a sharp pointed instrument, is inserted into a cannula assembly and used to puncture the peritoneum, i.e. the inner lining of the abdominal cavity wall. The gas provides a slight pressure which raises the wall surface of the peritoneum away from the vital organs thereby avoiding unnecessary contact with the organs by the instruments inserted into the cannula. This procedure also provides the surgeon with an adequate region in which to operate. Laparoscopic or endoscopic surgical instruments may then be inserted through the cannula to perform surgery within the abdominal cavity or other body portion. The cannula is also utilized for introducing tubes into the body as for drainage purposes or the like.

In view of the need to maintain the atmospheric integrity of the inner area of the cavity, a valve assembly which permits introduction of a trocar or any surgical instrument and which permits selective communication of the inner atmosphere of the cavity with the outside atmosphere is desirable. In this regard, there have been a number of attempts in the prior art to provide such atmospheric integrity.

One form of cannula assembly includes a valve assembly which includes a flapper valve which is pivotally mounted within the valve assembly and is automatically opened by the trocar or other object when it is inserted into the proximal end of the valve assembly. See, e.g., U.S. Pat. No. 4,943,280 to Lander.

U.S. Pat. No. 4,960,412 relates to a catheter introducing system which includes a valve assembly having dual flexible resilient gaskets which permit introduction of a catheter by providing dual openings which are dimensioned to contact a catheter tube introduced into the unit. Introduction of the tube is accomplished by introducing the tube into the openings of the gaskets. A first valve prevents or minimizes the flow of blood from the valve assembly unit when the catheter tube is absent and the second valve prevents or minimizes the flow of blood from the valve assembly when the catheter tube is present.

Another valve includes finger operated levers for controlling an inner valve formed of a plurality of radially movable members which join in adjacent relation to close the valve opening and which separate to permit entry of an element into the valve opening. The members are concentrically positioned and arranged to block the opening when the levers are at rest and to open in a manner to form a substantially circular passage-way when the levers are squeezed toward each other against the bias of a spring positioned therebetween.

Although attempts have been somewhat successful in providing a valve assembly which maintains the integrity of the atmospheric interface between the inlet of the valve assembly and the atmosphere outside the valve assembly, none have provided the degree of control to the user whereby opening adapted to facilitate the introduction of an instrument into the human body can be controlled selectively, opened or closed, in sequence and in a manner which positively retains the desired interface between the two atmospheres as may be required by the operator. The present invention provides a valve assembly which may be incorporated into a cannula assembly or utilized in combination with any type of tubular member for introduction into the body of a patient while permitting introduction of instruments into the body. At all times, the surgeon maintains control over the interface between the atmospheres within and without the patient's body. Moreover, the present invention makes it possible to introduce instruments of varying sizes into the body and insures the maintenance of a gas seal despite instrument manipulation therethrough.

SUMMARY OF THE INVENTION

A valve assembly adapted for introduction of an elongated object into a patient's body is provided which comprises first valve means formed of a resilient material and defining an aperture for reception of the object, the aperture being configured and dimensioned such that insertion of the object into the aperture will cause the resilient material defining the aperture to resiliently engage the outer surface of the object in a substantially fluid tight manner. Second valve means is positioned adjacent the first valve means in general alignment therewith, the second valve means defining an aperture in general alignment with the aperture of the first valve means and being formed of a flexible material at least in the

region defining the aperture. Means is provided to selectively permit the aperture of the second valve means to be opened or closed so as to permit entry of the object.

Preferably, the valve assembly comprises valve body means which defines proximal inlet and distal outlet openings. The first valve means is formed of an elastomeric resilient material and extends across the proximal inlet opening of the valve body, and defines an aperture configured and dimensioned for reception of the object in a manner such that resilient material surrounding the aperture engages the surface of the object to provide a substantially fluid tight seal which prevents passage of fluids past the interface. The second valve means is positioned adjacent and distally of the first valve means and both valve means extend across the proximal inlet opening of the valve body. The second valve means includes an aperture defined at least in part by flexible elastomeric material in general alignment with the aperture of the first valve means and of dimension sufficient to permit passage of the object after the object is passed through the first valve means. Means is provided to bias the flexible material defining the aperture of the second valve means to a configuration whereby the aperture is closed to form a fluid tight seal prior to inserting the object therethrough, and means is provided to open the aperture of the second valve means to permit passage of the object therethrough after the object is passed through the first valve means. Preferably, means to open the aperture of the second valve means is manually operable.

The objects contemplated are surgical instruments such as clip appliers, dissectors, graspers, laser and electrocautery devices, drainage or fluid introduction tubes or the like. The first valve means is positioned across the proximal opening of the valve body and the second valve means is positioned adjacent the first valve means and distally thereof. Further, the first and second valve means are preferably formed integrally of a flexible elastomeric resilient material, with the first valve means connected to the second valve means at the proximal ends thereof, the first valve means being positioned at least partially within the second valve means. The first and second valve means are joined at their proximal ends and are attached to the valve body across the proximal opening. The valve body includes a neck which extends distally of the distal end thereof, the neck defining an opening communicating with the interior of the valve body means. Further, the distally extending neck of the valve body is adapted to receive a tubular cannula such that the cannula extends distally of the valve body.

The second valve means comprises an elastomeric generally cylindrically shaped member which is preferably connected integrally at the proximal end thereof to the proximal end of the first valve means and is open at the distal end. The distal opening of the second valve means is capable of being closed by collapsing the distal end until the half portions thereof resiliently contact each other to form a substantial fluid tight seal. The distal end of the second valve means is biased toward the closed fluid tight position by a clamp which is positioned and adapted to bias the open end of the second valve means toward the collapsed configuration. The clamp comprises a pair of clamp blades, each blade connected to a portion of the distal open end of the second valve means. The clamp blades are each biased toward each other to close the distal opening of the second valve means by a respective torsion spring mounted within the valve body. Each clamp blade is connected to a pivotal arm and each pivotal arm is biased toward the position corresponding to the closed position of the second valve means. The pivotal arms are mounted for pivotal movement toward the valve-open position by reception into an aperture of at least one slidable pin. The pins are movable manually by engagement by the user's fingers.

The first and second valve means are preferably attached to and supported by an annular ring which includes a plurality of elongated fingers which extend distally therefrom and are positioned within the first valve means in contact with the inner surface thereof. The fingers provide an interface between the first valve means and objects inserted therein and assist in spreading the opening of the first valve means for entry of the instrument. Further, the fingers distribute the force over the inner surface of the first valve means.

Each slidable pin has a frusto-conical shaped tip adjacent each pivot arm for engagement with the respective pivot arm when the pins are moved toward each other by manual action of the user. Further, the valve body is preferably a two piece valve housing assembled at a medial interface and constructed of a relatively rigid plastic material such as polycarbonate, polyethylene or the like.

In a preferred embodiment, a cannula and trocar assembly is provided for puncturing a body wall of a patient for the introduction of elongated objects as surgical instruments or the like into the body of the patient while maintaining a substantial fluid tight seal between internal body portions and the outside atmosphere at all times prior to and after insertion of the object. The valve housing has an inlet opening at the proximal end and an outlet opening at the distal end, the distal end opening having a tubular cannula extending distally therefrom. A trocar is positioned within the valve housing and the cannula for puncturing the body wall. Thereafter, the trocar is removed and elongated objects such as surgical instruments or the like may be introduced into the patient's body through the valve assembly and cannula as described hereinabove.

In the preferred embodiment the first and second valves are molded integrally of synthetic or natural rubber and are connected at a common proximal end which defines the proximal opening. The first valve means has a generally conical shape and is positioned within the second valve means in a generally concentric fashion. The valve means are mounted onto a support ring which is used to mount the valve means to an annular portion within the valve housing.

A method is provided for selectively sealing a valve assembly for communication with inner portions of a patient's body while permitting introduction of an elongated instrument therethrough, the valve assembly having a proximal inlet opening and a distal outlet opening, comprising providing first valve means comprised of resilient material defining an opening which permits entry therethrough by the instrument while resiliently contacting the outer surface, providing second valve means distal of the first valve means, and selectively controlling the open and closed condition of the second valve means to permit passage of the instrument after entry through the first valve means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded perspective view of a cannula assembly illustrating the valve assembly constructed according to the present invention;

FIG. **2** is a view of the lower housing half section shown in FIG. **1** with portions of the inner valve and cannula cut away for illustration purposes;

FIG. **3** is a cross-sectional view of the valve assembly of the present invention taken along lines **3—3** of FIG. **2**; and

FIG. **4** is a cross-sectional view of the valve assembly of the present invention, taken along lines **4—4** of FIG. **2**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention contemplates introduction into a patient's body of all types of surgical instruments including clip appliers, lasers, photographic devices, tubes, etc. All such objects are referred to herein as "instruments".

Referring initially to FIGS. **1** and **2**, a cannula assembly **10** is illustrated having the novel valve assembly **12** constructed according to the present invention. Valve assembly **12** includes a valve housing **15** formed of upper housing half section **14** and lower housing half section **16** shown separated in FIG. **1** for convenience of illustration.

The housing half sections **14,16** are formed of a suitable desirable plastic material such as polycarbonate, polyethylene or the like. One preferred material is LEXAN brand polycarbonate manufactured and marketed by General Electric Company, Pittsfield, Mass. The housing half sections **14,16** are normally attached along the seam by suitable attachment techniques such as adhesive, ultrasonic welding, or the like.

The valve housing **15** includes neck **18** at the distal end having an aperture **20** dimensioned for reception of an appropriate sheath tube such as cannula **22** to form the cannula assembly **10**. The proximal end of valve housing **15** includes inlet opening **24** which includes annular partition **26** for supporting a dual diaphragm as will be described.

Referring now to FIG. **2**, the lower housing half section **16** is shown with the upper housing half section **14** removed, so as to illustrate the novel inner valve mechanism of the present invention. The valve mechanism is shown partially cut away and in cross section. Dual flexible elastomeric sealing diaphragm **30** extends across the aperture **20** of housing **15** as shown. The diaphragm **30** forms a circular rib **33** which fits tightly by snap fit onto annular partition **26** with dual flanged circular rib **32** as shown in FIG. **2**. The annular partition **26** is constructed of the same relatively rigid plastic material such as polycarbonate, polyethylene or the like, as the valve housing, while diaphragm **30** is constructed of an elastomeric material such as synthetic or natural rubber. Diaphragm **30** is of dual walled construction as shown, with the inner wall **30*a*** having a central aperture **34** for reception of an instrument as will be described.

Referring now to FIG. **1** in conjunction with FIGS. **3** and **4**, outer wall **30*b*** has formed at the distal end, a pair of ears **36,38** which are connected to clamp blades **40,42** as shown, by suitable pivot pins **44,46** and attachment nuts **43,47**. Each clamp blade **40,42** is biased in a direction toward the other by a torsion spring **48,50** having one leg in engagement with the adjacent housing wall and the other leg in engagement with pivotal arm **52,54** respectively pivotally mounted at pivot pin **56,58** as shown in FIG. **3**. Each pivot arm **52,54** extends as shown, into the path of a pin **60,62** which is slidably mounted within elongated opening **64,65** having a circular cross-section similar to the cross-section of the pins **60,62**. The inner end of each pin has an opening **66,68** for reception of the appropriate pivotal arm **52,54** such that manually depressing the slidable pins **60,62** toward each other by engagement of transverse buttons **70,72** with the thumb and index finger causes pivotal arms **52,54** to pivotally rotate arms **52,54** away from each other. This motion causes clamp blades **40,42** with ears **36,38** to separate causing outer wall **30*b*** of dual diaphragm **30** to open at the distal end to the configuration shown in FIG. **1**. When the pins **60,62** are released, the outer wall **30*b*** of diaphragm **30** collapses to the configuration shown in FIGS. **3** and **4** under action of clamp blades **44,46** and springs **48,50**, thus causing outer wall to collapse to the duckbill shape **74**, providing a fluid tight seal between the proximal end of the diaphragm **30** and the distal end.

Referring now to FIG. **4** in conjunction with FIG. **1**, inner elastomeric wall **30*a*** of diaphragm **30** defines circular central aperture **34** at the distal end which is dimensioned less than or equal to the outer diameter of any instrument intended for entry into the proximal end of the valve assembly. Preferably, diaphragm **30** is fabricated from a material which is sufficiently resilient to accommodate and provide a fluid seal with instruments of varying diameters, e.g., diameters of from 5 mm to 10 mm. In FIG. **1** an endoscopic clip applying apparatus is shown at **76**. However, any elongated relatively narrow instrument is contemplated.

Referring once again to FIG. **3** in conjunction with FIG. **1**, diaphragm mounting and stabilizing device **31** is formed of dual flanged circular ribbed ring **32** having distally extending fingers **78** tapered at their free ends as shown. Diaphragm **30** is mounted to dual flanged circular ring **32** as shown in FIG. **4** and the entire assembly is mounted to annular partition **26** as shown. Fingers **78** are positioned within diaphragm inner wall **30*a*** and are sufficiently flexible to conform to the shape of the inner wall while providing some degree of stability to the inner wall. Fingers **78** also assist in spreading inner wall **30*a*** to expand aperture **34** when an instrument is inserted by distributing the spreading force more evenly. In addition to facilitating expansion of aperture **34** to conform to instrument **76**, fingers **78** minimize the risk of damage to elastomeric inner wall **30*a***, e.g., puncture thereof, by providing an interface between the instrument **76** and the inner wall. Stabilizing device **31** is fabricated of a suitable flexible plastic material such as polyester, polypropylene, etc. and fingers **78** are preferably formed integral with dual flanged ring **32**. Further, fingers **78** are sufficiently thin and flexible such that insertion into inner wall **30*a*** of diaphragm **30** causes them to assume an initial arcuate shape as shown in FIGS. **2** and **4**, similar to the generally conical shape of inner wall **30*a***.

Upon insertion of instrument **76** into housing opening **20** and through aperture **34** of inner wall **30*a***, the elastomeric material of wall **30*a*** will expand or stretch around the instrument **76** to form a fluid tight seal. The seal is of sufficient fluid tight character that media such as pressurized gases used to insufflate a body cavity or body liquids will not pass the interface between diaphragm inner wall **30*a*** and the instrument **76**. Aperture **34**, in its non-expanded or non-stretched condition, is typically approximately 3 to 15 mm to accommodate elongated endoscopic instruments while maintaining sufficient sealed contact with the other surface thereof. However, such dimensions will vary depending upon the size of the instruments and the intended application. Further, manipulation of the instrument in any direction will not affect the seal, since the elastomeric material will remain in tight contact with the outer surface of the instrument.

At the point when the instrument **76** has passed the inner wall **30*a*** and entered aperture **34**, a gas tight seal has been created between the instrument and the inner wall **30*a***. The surgeon then squeezes pins **60,62** with the thumb and index finger causing the distal end of outer wall **30*b*** of diaphragm **30** to expand to the shape shown in FIG. **1** thus permitting continued entry of the instrument **76** through the entire valve body housing **15** and into the cannula **22**. Depending upon the particular procedure, the surgeon may prefer to squeeze pins **60,62** thereby opening outer wall **30*b*** prior to entry of instrument **76** into the valve housing **15** and into diaphragm inner wall **30*a***.

Cannula **22** is connected to the distal end of the valve housing at neck **18** which has a series of alternating circular shaped ribs **80** and valleys **82**. Cannula **22** is fabricated of a rigid material such as a plastic, fiberglass or metal and is supported in position as shown in FIGS. **2** and **4** within neck **18** by the ribs **80** which are formed of the same material. Alternatively, the tube **22** may be of elastomeric material in which case it would simply be flexible and resilient so as to be assembled with distal neck **18** by inserting the tube into the neck and distorting the outer shape until it is snapped into position as shown within ribs **80**.

The operation of the valve assembly will now be described. The valve assembly is intended to be supplied as part of a cannula assembly, i.e. a valve assembly with distal cannula tube **22** positioned as shown. A trocar is a sharp pointed instrument usually fitted within a cannula assembly and used to insert the cannula into a body cavity by first piercing an aperture in the cavity wall (i.e., the peritoneum). The cannula is then inserted into the punctured body wall of the patient. Thereafter, the trocar is removed, permitting insertion of instruments into the patient's body through the cannula to perform the desired procedure. Thus, the significance of providing control to the surgeon of the sealed state of the opening in the cannula assembly cannot be overemphasized. Such opening will ultimately control the exposure between the internal part of the body cavity and the outside atmosphere. For laparoscopic procedures the valve assembly will preserve the state of insufflation of the peritoneum during the surgical procedures.

The surgeon removes the trocar from the cannula assembly thereby permitting the opening of outer wall **30*b*** of diaphragm **30** to close automatically under the action of springs **48,50**. Thereafter, the surgeon inserts an instrument into the body cavity by first inserting it into the proximal end of the valve assembly, through dual flanged ring **32** and then through aperture **34** of inner diaphragm wall **30*a***. Pins **60,62** may be selectively squeezed as desired by the surgeon to open the distal end of outer wall **30*b*** to permit entry of the instrument into cannula **22** and into the body cavity. At this point, the tight contact between the instrument **76** and the diaphragm inner wall **30*a*** at aperture **34** has sealed the inner body cavity from the outside atmosphere. This seal is provided by the resilient property of the stretched elastomeric material surrounding opening **34**. Thus, separating clamp plates **40,42** to open outer diaphragm wall **30*b*** to permit entry of instrument **76** into cannula **22** does not affect the sealed condition of the inner anatomical cavity. As noted previously, manipulation of the instrument in any direction will not affect the seal, since the elastomeric material defining the opening **34** will conform to the movements of the instrument and assume an elliptical or other shape necessary to maintain contact.

As noted, aperture **34** is preferably dimensioned between 3 and 15 mm to accommodate laparoscopic and endoscopic instruments such as clip appliers, laser tubes, photographic instruments, tubes or the like. However, depending upon need or application this dimensional range may be varied to accommodate any particular instrument.

The opening at the distal end of outer wall **30*b*** is always under the surgeon's control through pins **60,62** and is adapted to be automatically actuated to the closed duckbill shaped position **74** under action of springs **48,50** when the surgeon removes the instrument **76** or other object from the valve assembly. Further, manipulation of the instrument **76** does not affect the shape of aperture **34** or the sealing contact of inner wall **30** or with the instruments because diaphragm **30** is sufficiently flexible and resilient to maintain contact with the surface of the instrument **76**. Thus, during the entire sequence the integrity of the seal between the inside of the body cavity and the outside atmosphere is clearly maintained at all times.

We claim:

1. A trocar assembly having a channel defined along an elongate axis, the trocar assembly being adapted to receive an instrument having a particular cross-sectional dimension, said trocar assembly comprising:

an elastomeric septum disposed in said channel and including portions defining an orifice having in a relaxed state a first cross-sectional area and in an expanded state a second cross-sectional area; and

means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area.

2. The trocar assembly as recited in claim **1** wherein said first cross-sectional area is greater than zero.

3. The trocar assembly as recited in claim **1** wherein said second cross-sectional area is smaller than the particular cross-sectional area of said instrument.

4. The trocar assembly as recited in claim **1**, and further comprising a seal housing adapted to receive the elastomeric septum, the septum having seating portions positioned radially outwardly of the orifice-defining portions and contiguous therewith, said seating portions being attached to said housing for seating the septum therein,

wherein the seating portions are disposed in a first plane and said orifice-defining portions are disposed in a second plane, said first and second planes being spaced along said elongate axis.

5. A valve assembly adapted to receive an instrument having an outer surface and a cross-sectional dimension, comprising:

a housing defining a channel extending therethrough along an elongate axis;

a septum disposed in said housing and adapted to extend across said channel, portions of the septum defining an orifice communicating with the channel through the septum;

at least said portions of the septum being formed of an elastomeric material and being expandable radially outwardly to enlarge the orifice; and

means pivotal on said housing and engaging the septum outwardly of the orifice for enlarging the orifice, said enlarging means being responsive to the instrument for enlarging the orifice in proportion to the cross-sectional dimension of said instrument.

6. A seal assembly adapted to receive an elongate object and to form a seal around the object, the assembly comprising:

a housing defining a channel configured to receive the object moving generally axially through the channel;

a septum extending across the channel of the housing and forming an outer seal with the housing;

portions of the septum defining a hole in communication with the channel on both sides of the septum, the hole

having a size sufficient to receive the object with the hole portions forming an inner seal with the object;

the septum being formed of an elastomeric material having properties for producing a friction force which resists movement of the object through the septum; and

means responsive to insertion of the object into the channel for reducing the friction force on the object.

7. The assembly as recited in claim **6** wherein the friction reducing means comprises:

means responsive to insertion of the object into the channel for measuring a particular dimension of the object; and

means for stretching the septum in proportion to the particular dimension to enlarge the hole and thereby reduce the friction forces between the septum portions and the object.

8. The assembly recited in claim **7** wherein the friction reducing means further comprises:

a frame;

a plurality of levers each pivotal on the frame and engaging the septum to move the hole portions radially.

9. The assembly recited in claim **8** wherein the frame is annular and the friction reducing means is disposed transverse to the channel in the housing.

10. A trocar assembly adapted to receive an instrument having a particular cross-sectional dimension, said trocar assembly comprising:

a housing;

an elastomeric member disposed within said housing and defining an orifice having in a relaxed state a first cross-sectional area and in an expanded state a second cross-sectional area; and

means responsive to the particular dimension of the instrument for expanding said orifice to the second cross-sectional area.

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